Applying bioethics : local research ethics committees and their regulation of medical research

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Applying Bioethics: Local Research Ethics Committees and their ethical regulation of medical research

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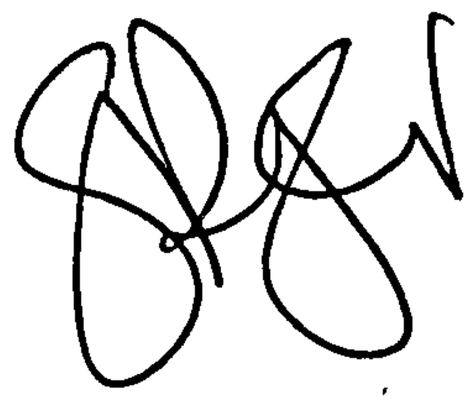
Declaration

I declare that this thesis is my own work and has not been submitted in any previous application for a degree. Contributions have been acknowledged.



Abstract

This thesis examines the moral deliberations of Local Research Ethics Committees (LRECs) responsible for ethically reviewing research protocols involving human subjects in the NHS. By examining the embodied social contexts in which LRECs perform their review, it challenges the prevailing assumption of professional bioethicists (enshrined in government regulation) that the ethical dilemmas posed by medical research are best resolved in the abstract using the tools of analytic philosophy. Instead, it follows recent work in feminist theory and science studies by understanding medical ethics as a form of situated knowledge and reasoning. Rather than bracketing off the context in which ethical issues arise and are settled, it takes those human geographies as inextricable from and fundamental to the framing of and deliberating upon moral questions.

Thus, in exploring the moral deliberations of LRECs the thesis combines empirical analysis of their decision-making practices with the methods of analytic philosophy to assess the moral 'work' performed by LRECs. Using ethnographic methods of participant observations of committee meetings and follow-up interviews with committee members, it focuses on the principle of informed consent (and the value of individual autonomy it enshrines), on roles of lay participation in LREC deliberations, and on how particular concerns are framed as local or ethical (and thus within the LRECs' purview) as opposed to epistemological or scientific (and thus beyond it). Thus providing an in-depth analysis of these important sites where bioethics is applied, and asking whether and how practical demands should inform the development of normative bioethical theory.

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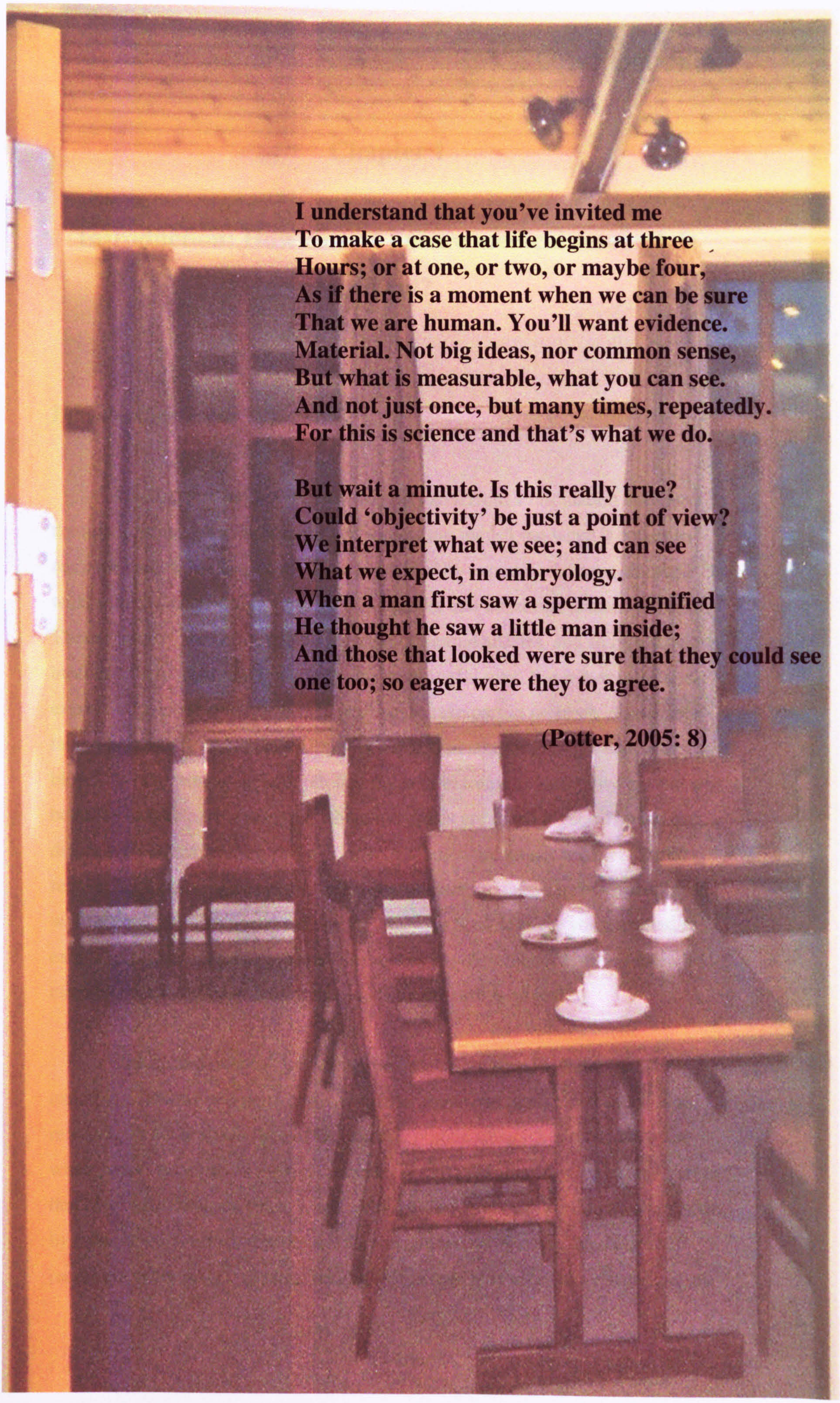
This thesis is dedicated to Penny Robson
And to the memory of Do Colvin


I understand that you've invited me
To make a case that life begins at three
Hours; or at one, or two, or maybe four,
As if there is a moment when we can be sure
That we are human. You'll want evidence.
Material. Not big ideas, nor common sense,
But what is measurable, what you can see.
And not just once, but many times, repeatedly.
For this is science and that's what we do.

But wait a minute. Is this really true?
Could 'objectivity' be just a point of view?
We interpret what we see; and can see
What we expect, in embryology.
When a man first saw a sperm magnified
He thought he saw a little man inside;
And those that looked were sure that they could see
one too; so eager were they to agree.

(Potter, 2005: 8)

Chapter 1

Introduction: How can we ensure medical research is ethical?

Introduction

The impetus for this research project came from a fascination with how the relationships between science and society are played out when it comes to our own bodies. Medical research is conducted by experts, who are enmeshed within the understandings, practices, and places that constitute science in action. These research protocols, results reported in journal articles, and so on are simply inaccessible to most other people in any meaningful way. But it is we, the non-experts, who must decide whether we want to take part in research. Sometimes taking part will be innocuous: filling in a questionnaire or giving a little extra blood. At other times, though, often at times of extreme vulnerability, people will be asked to take part in research where the stakes are much higher. Having been diagnosed with cancer are you willing to test a new treatment regime? While recovering from a major operation are you prepared to take part in research that will be time consuming and exhausting? In your final days are you prepared to extend unpleasant treatment to see if it makes any difference? How, in these circumstances are we to ensure that medical research is ethical?

One approach is to clarify the principles we wish to uphold, like, for example, allowing people to choose whether they want to take part in medical research. In other words, one of the most important things that should happen when people take part in medical research is that they should agree to take part in that research. There are times when we might feel that this rule can be overridden by other considerations. On the whole, though, we see this as a fundamental requirement for ethical medical research. If people give extra blood samples, test

a new drug, or answer a questionnaire they should do so in the knowledge that the procedure is part of a research project and not their treatment. They should be told what is involved in taking part in the research and what is not. For example, a patient should not take part in research because they are under the erroneous impression that by doing so their condition will be monitored more closely than it otherwise would be. This imperative, for people to agree to take part in research, is fundamental. It has been formalised in the requirement for researchers to obtain an 'informed consent' from research subjects and one strategy for ensuring medical research is ethical is to clarify the importance and the reach of such a principle.

Another approach, the one I adopt, is to forefront and seek to understand the spaces in which the ethical issues arising from medical research are encountered and solved. While abstract principles are obviously important, it is equally important that we do not let them obscure all other aspects of ethics. The 'applying' of principles is an active and contingent endeavour. Who applies them, under what conditions, and where are all-important in whether what is produced is ethical.

In this thesis, I examine one of the spaces in which problems of medical research are understood and addressed. As I wanted to consider the socio-political nature of medical research, the wider relationships beyond the immediate expert-patient exchange, I chose to investigate a node in the network of regulation governing the ethics of such research. To that end, I have produced a description of the 'emplaced' ethics of Local Research Ethics Committees (LRECs). In chapters three and four I describe in detail the history and governance of these committees and their current practices. Briefly, though, Research Ethics Committees (RECs), of which LRECs are one type, are part of the structure of the regulation of medical research. They are committees that exist within the structure of the NHS and are made up of between 10 and 20 members, mostly health professionals. Committees meet to discuss proposed research projects and to review the ethical aspects of the research. No research can take place involving NHS staff, patients, or premises without prior research

ethics committee approval. Thus, LRECs are an important site in the production of ethical medical research.

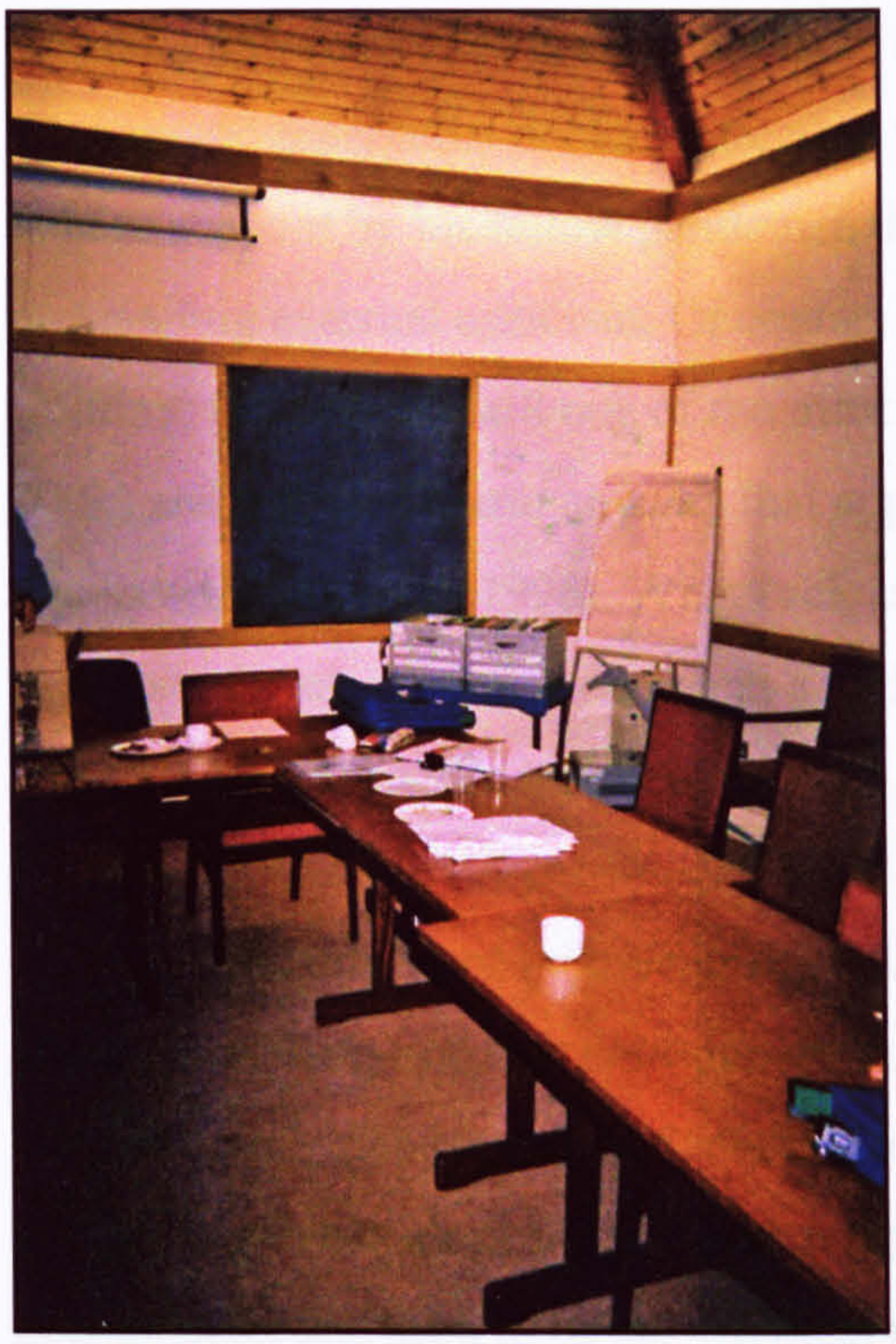


Figure 1.1 A meeting room

Figure 1.2 A LREC at work

LRECs operate within a wider context of medical regulation. LRECs are one mechanism that has emerged for mediating relationships between doctors,

patients, and the State in the context of a mistrustful, or at least potentially mistrustful, lay public. While it is wrong to project on to history an over-simplified doctor-patient relationship of the past the appearance of ethical review signals a different tenor in this three-way relationship. The caricature has the Hippocratic-paternalist doctor as treating trusting and grateful patients and being held to account by his fellow gentlemen doctors, the cloak of 'expertise' prescinding external criticism. Of course, such a straw doll will not hold up to scrutiny. Doctors are still one of the most trusted of all professions (MORI, 2001) and we have learnt anyway that apparent trust can hide relationships of dependency (Wynne, 1996). What is clear though is that there was enough public mistrust of research for government and the medical professions to feel that it was an issue that needed addressing.

As examples of failures in strong Hippocratic self-regulation occurred and a globalising research environment made new demands on the system, new ways to regulate medicine, and medical research in particular, had to be found. It is the accepted wisdom of the day that regulatory systems must be open and accountable, and seen to be so. Medical research, if it is to operate in the current climate, must make itself more accountable to outsiders than a Hippocratic-paternalist doctor and his peers were. Commenting on the climate in which doctors operate the Editor of the *British Medical Journal* said:

> We live in a world where what is closed is immediately suspect. Lack of transparency implies incompetence, corruption, or bias. (Smith, 2001: xii)

Professional guidelines and regulation have proliferated in an attempt by "doctors to demonstrate their trustworthiness through open accountability to the public" (Hill, 2000: 1). Guidelines and regulation, it is argued, provide the opportunity to protect patients' rights by holding doctors accountable (Sharpe, 2000) as well as securing patients' trust. Regulation acts to both reassure the public that past mistakes cannot happen again and provide an aura of openness and accountability.

Ethical review promises such a mechanism for accountability. As it has developed ethical review has had to respond to the need for 'administrative objectivity'. Standardising administrative procedures creates what Porter (1995: 90) calls a "technology of trust" – a set of rigid, impersonal, and in that sense mechanically objective procedures serving as an alternative to personal trusting relationships. Predictable outcomes are secured through standardised rules and decision-making criteria. These outcomes are objective in the sense that they are not subject to the vagaries and subjectivity of the person(s) bringing about the outcome.

There is the constant danger that regulation colonises the site it governs. The first consequence of this colonization is that the logic of regulating changes the understandings of what is being regulated. When regulation becomes a dominant reference point the micro rationality of the 'checking up' and 'making accountable' subverts the macro reality of what is being checked (Power, 1997: 121). Secondly, the nature of the assurance given by regulation is made ambiguous (Power, 1997:28). Promises of accountability and openness become at best vague. Describing audit but highlighting concerns that ought to be raised with reference to other regulatory processes, Power (1997: 27) notes that, "the fact of being audited deters public curiosity and inquiry and the users of audit are often just a mythical reference point within expert discourses. Audit is in this respect a substitute for democracy rather than an aid to it". The process that was supposed to create accountability, might, do little to do so and in the process actually subvert the meaning of the very thing it was supposed to make accountable.

For LRECs - spaces of regulation, of expertise, and of accountability - applying principles, such as the importance of informed consent, is not straightforward. The main claim of this thesis is that the ethical deliberations of LRECs, and the rulings they make, cannot be understood by recourse to abstract reasoning. We need to seek to address their emplaced bioethics.

Methods

In order to explore ethical deliberations as a form of emplaced bioethics, I used three main data sets – survey, observations of committee meetings, and interviews with committee members. These main data sets are supplemented with additional interviews with representatives of the Central Office of Research Ethics Committees and those engaged in training LREC members, my own participation for 18 months on an LREC as a lay member, and attendance on training courses (see appendix eight). Due to limited space the results of these supplementary methods are not discussed directly but used, rather, to inform my analysis of the main data sets.

In contrast to past research on LRECs the evidence I use is primarily ethnographic 'thick' descriptions (Baxter and Eyles, 1997, Hammersley and Atkinson, 1995). Before outlining my research methods, I first describe the methods of past research into LRECs.

Methods of past research conducted on LRECs

This thesis is the first large scale investigation of LRECs for over a decade. In the past, research tended to focus on the idiosyncratic practice of the committees (Foster, 1999; 219, Neuberger, 1992, Godfrey et al., 2001), with a few smaller studies conducted on the nature of their decisions (Kent, 1999, Kent, 1997, Thompson et al., 1981, Allen and Water, 1982, Foster, 1999, Neuberger, 1992). The methods of questionnaire survey figured highly (Neuberger, 1992, Nicholson, 1986, Holley and Foster, 1998), as did documentary analysis of the annual reports of LRECs (Godfrey et al., 2001, Foster et al., 1995), meeting minutes and correspondence (Allen and Water, 1982, Kent, 1999), consent forms and research records (Smith et al., 1997a), and application forms and guidance to researchers (Holley and Foster, 1998). In addition to investigating LREC practice itself some research has been undertaken to investigate patients' and researchers' understanding of LRECs (Kent, 1997, Berry, 1997).

Past research has been conducted on different scales. In 2001 225 LRECs existed (Godfrey et al., 2001). Surveys investigating the idiosyncrasies of practice have aimed to elicit responses from all LRECs (Godfrey et al., 2001, Neuberger, 1992, Foster et al., 1995). Conversely, there have been small projects that looked at just one committee across time (Allen and Water, 1982), or in depth with a sample of committees (Kent, 1999, Neuberger, 1992, , 1996).

Very little qualitative research has been undertaken on LRECs. As I explain in chapter three, LRECs are also part of a wider system that also includes Multi-centre Research Ethics Committees (MRECs). In her MSc dissertation, Duckworth (2002) undertook discourse analysis of two MREC meetings examining the contribution of lay members. More recently, Corrigan (2000) used participant observation to investigate LRECs. One chapter of her thesis is dedicated to LRECs but, due to problems with confidentiality, the chapter is very light on detail.

This thesis seeks to rectify this paucity of information on the conceptualisations and decision making of LRECs.

Survey

As there was no data in existence on the constitution of LRECs at the time of my research I conducted a questionnaire survey of all LRECs in the UK (Central Office for Research Ethics Committees, 2002a). I surveyed all 218 LRECs in the UK to ascertain their constitution and working practices. I contacted all committees listed on the Department of Health's Central Office for Research Ethics Committee on 01/11/02 (see appendices nine and 10). The survey consisted of a questionnaire to administrators and one to each committee member. The former had a response rate of forty-four percent. If the number of committee members reported in these surveys is representative, the response rate for the questionnaires to committee members was twenty-five percent. I discuss the results of this survey in chapter three, as well as drawing on them more reflectively in other chapters.

Observations of LREC meetings

I attended 20 committee meetings as an observer. One committee I observed twice because a member I was due to interview was unable to attend the first meeting and so I was invited to attend another meeting he would be attending. In total, then, I observed 19 committees in addition to the committee I sat on myself as a lay member. The committees that took part in this in-depth stage of the research were recruited in light of the survey results, to represent a broad range of committee types. I wanted to observe committees attached to large metropolitan teaching hospitals and also primarily rural health authorities, LRECs with both many and few lay members, committees that met for only an hour and one that had meetings that went on for hours. I used the questionnaire survey I conducted as a springboard to such broad based recruitment (see appendix one for the observed committees' questionnaire results). The observed committees are broadly typical of LRECs in general (in terms of size, lay membership, length of meeting, and applications per meeting) with the proviso that the committees I observed are more likely to be smaller, have slightly more lay members, shorter meetings, and review less applications per meeting than the LRECs as a whole (see appendix two). I also wanted to observe LRECs from across the country (appendix three). I wanted, though, to target particular areas. I was interested in observing LRECs in areas where there had been a scandal about ethics in medical research, areas of the country with particularly bad health (Shaw et al., 1999), and areas where in the summer of 2001 there had been race riots (BBC news, 2001). By targeting committees in these areas of the country it did mean that other areas of the country were neglected.

In most observations it was when the chair called the meeting to order that I was introduced to the committee. The chair generally introduced me by telling everyone my name, that I was doing Ph.D. research at King's College, London, and that I was interested in LRECs. Interestingly, I was rarely introduced to researchers who were attending the meeting. Where I was, it was as an observer. I think that often committee members assumed that I was linked with the Centre of Medical Law and Ethics (CMLE) at King's. LREC members have come across this centre as it provides much of the training for research

ethics committee members and edits the *Manual for Research Ethics Committees*. When I introduced myself I said I was based in the geography department, an admission that was generally met with puzzled looks. LREC members' interest in this (as they saw it) anomaly quite often was the first topic of our subsequent interviews. The committee introduced themselves, going round the table they usually said their name and in what capacity they sat on the committee (GP, pharmacist, statistician etc). In lots of the committees I attended members had name labels making note taking much easier.

In a handful of cases I was asked to sign a confidentiality form, either at the beginning or the end of the meeting. On one occasion a committee chair contacted me on the day after the meeting seeking reassurance that I would not disclose details of their discussion as she felt it was particularly sensitive. After another committee observation the administrator contacted me after a meeting saying that the chair had been concerned that I had been taking notes during the meeting. The committee, she said, had agreed to have me in the meeting as an observer and, observers observe; they do not also take notes.

I sat at the table with the committee apart from on one occasion when I was asked to sit at the back of the room. There were only one or two times where I was addressed during a meeting. This was when there was a disagreement on the committee, followed by an uncertainty about practice and I felt the chair was uncomfortable about an observer witnessing this. Overall, I felt assured that it was 'business as usual' despite my presence.

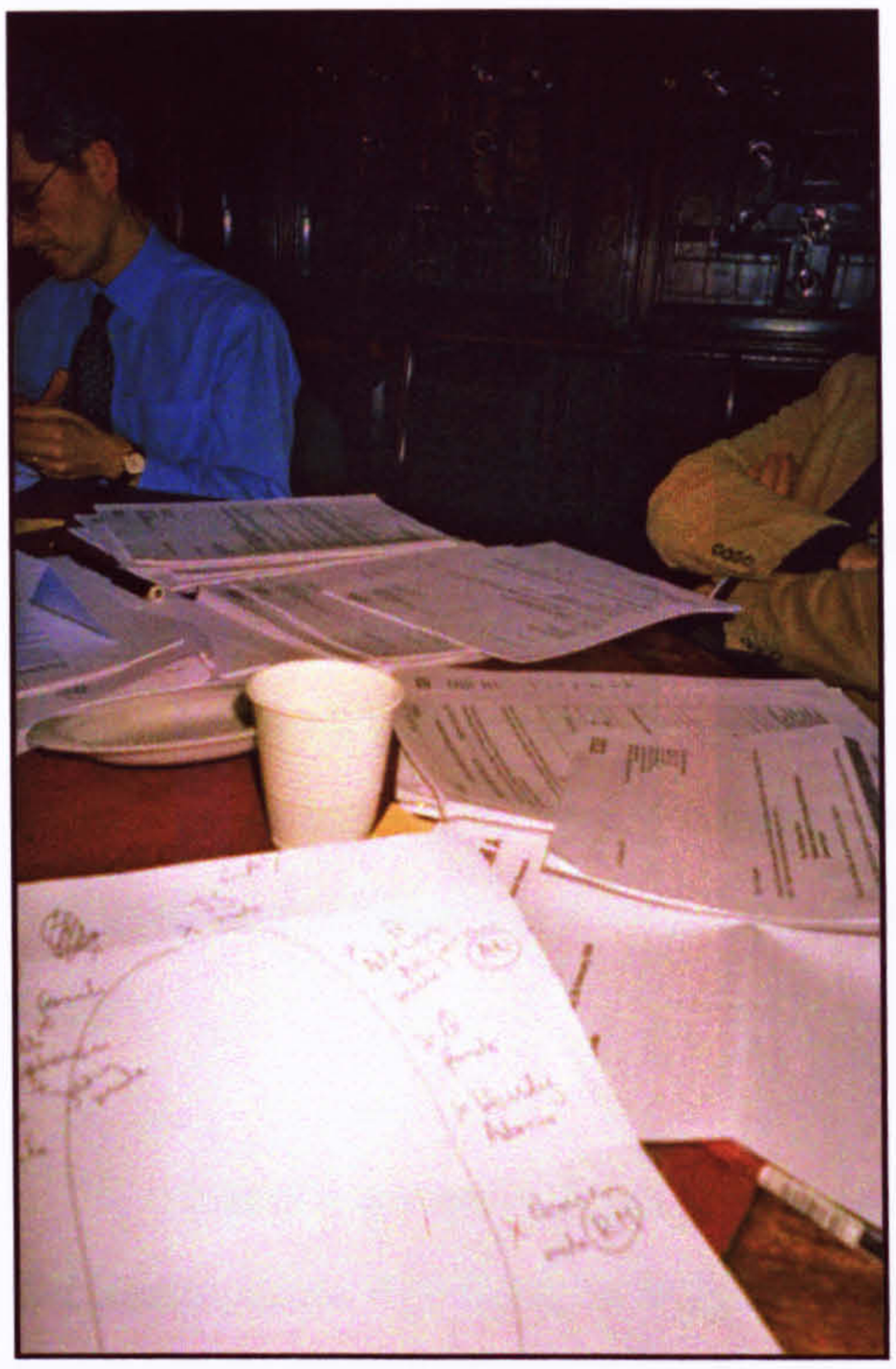


Figure 1.3 My field notes

In every committee meeting I attended I took field notes where I wrote down what was going on, who said what, which points were raised, and which were effective. I used these notes to produce maps of each meeting's issues. These maps formed the basis of the interviews I conducted with a sample of committee members after the meeting.

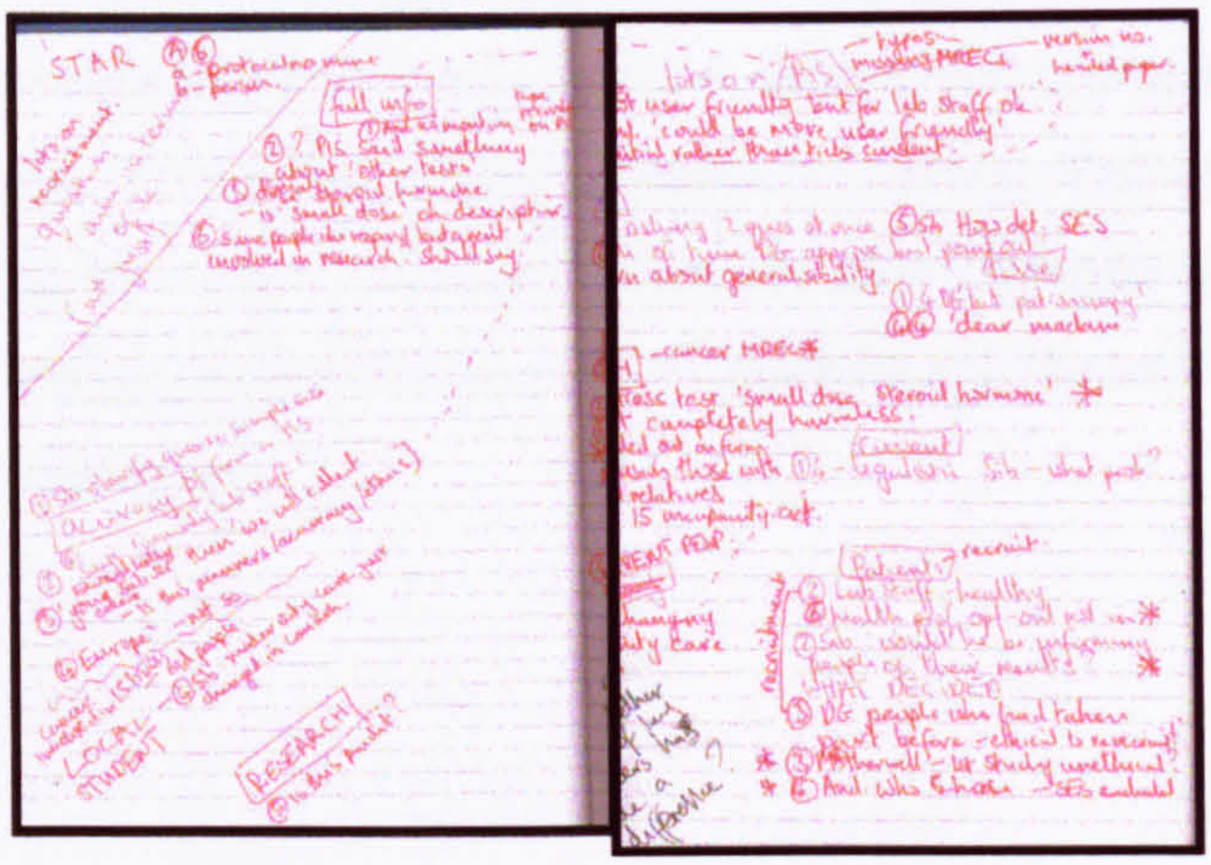


Figure 1.4 A map of a meeting

Interviews

I interviewed 49 members of LRECs. I aimed to interview at least one expert and one lay member of each meeting I observed and overall to interview a good spread of different types of professional members. On one occasion I was not able to interview any members who attended the meeting. The members who had said they were happy to be interviewed dropped out. I went ahead with the observation anyway because the committee was attached to a big teaching hospital. For all other observations I was able to interview at least one committee member (see appendix one). Where I quote interviewees I use a C (to indicate 'committee member') and then a number which refers to the table in appendix four.

Interviews were conducted as soon after the meeting as possible so that the issues were still fresh in both the interviewees' minds and my own. Interviews were semi-structured and lasted about an hour. Through these conversations I explored members' understandings of and attitudes towards LREC review. In this way I was able to triangulate my own account, based on 'my having been there' (Clifford, 1988), with the committee members' accounts of what had happened in the meetings. When I began the interviews I had a protocol that concentrated on three areas: the member's biography, their experience of being a member, and their views about medical research (appendix five). I soon realised that discussing medical research in the abstract is not very informative, as members simply repeat general principles parrot fashion. I considered revising the interview protocol to include discussing imagined vignettes. It was at that point that I developed the method of attending meetings and conducting associated interviews. It seemed silly to discuss hypothetical bioethical situations with members when I could discuss the real ones they were making decisions about.

Researching research ethics

Undertaking a research project about research ethics has created an interesting and sometimes awkward position for me as a researcher. Much has been said about the disruption of any notion of an independent and autonomous researcher. Often this centres around explications of informants as the 'expert' concerning the topic that is being studied (the social scientists' own recognition of the value of 'lay' knowledge). Such considerations are assumed to invoke humility in the researcher. It has been very clear to me, however, that not only are my informants experts concerning the substantive content of my research, they also feel themselves more than capable of commenting on the ethics and more interestingly on the design of this project, a circumstance, which initially and when I received particularly passionate criticism, invoked feelings not of humility but discomfort and anxiety. Furthermore, these feelings are exaggerated because the subject of ethics is an emotive one: nobody wants to be told, as I have been on more than one occasion, by an expert in ethical review that your research is unethical.

I have dealt with the ethical issues raised by this project as seems fit to me in light of research methods training and my immersion in academic social science (primarily British human geography and some medical sociology), and, where I have been unsure, in the light of advice that I have sought out. As social science research this project is notable in that it raises none of the ethical issues that often arise from empirical work in human geography or medical sociology. I am not dealing with any politically, economically or culturally vulnerable groups in society; no patients, children, very old people, displaced people, poor people and so on. The informants that I am seeking to recruit are well-educated, more often than not professionals, by definition people who are able to speak for themselves. Furthermore, as they are well versed in research practices themselves, always older than me and more often than not having, what might be termed, more power and social status than me, as a researcher the likelihood of me exploiting them is small.

There are ethical questions raised by any research project though. When I have sought advice on ensuring ethical soundness from experts in this field in sociology I have been referred to the British Sociological Association's Ethical Code (British Sociology Association, 2002), with which I believe this project complies. I have found the most interesting and troubling issues to be raised not by confidentiality of interview data, or anonymity of informants but by my involvement as a lay member on a committee. The insider/outside position is a difficult one to take. I found myself troubled by issues such as whether other committee members always 'remember' that I am not just another member of the committee and whether me asking to be sent on as much training as I was did, the best use of NHS resources. These are not issues that I ever resolved. I do not, though, find fieldwork a 'morally dubious' activity in itself, as Bosk (2001: 205) warns that it is. It can, though, be fraught, in that '[a]s a human activity, fieldwork is most peculiar because it contravenes so many of the ordinary rules of everyday social life'. If we are ever to conduct empirical research we must be mindful of these issues but not be paralysed by them.

Having described my own reflections on researching research ethics I want to go on to highlight some of the specific issues raised by my project and the reactions that I have had from informants. Perhaps the most notable reaction has been that this research project ought to have undergone NHS ethical review itself. Indeed the Governance states that:

> Ethical advice from the appropriate NHS REC is required for any research proposal involving: NHS staff – recruited as research participants by virtue of their professional role. (Department of Health, 2001a: 3.1 g)

I have not sought out ethical approval though. I have not done so for many of the reasons that cause other researchers to be reticent about RECs: the time and work involved, not wanting to change my research plan, the feeling that RECs had nothing to add to my own consideration of the issues. At the beginning of the research it did not occur to me to seek approval. I simply had not come across geographers applying to ethics committees. As the research progressed and

people were prepared to talk to me without ethics approval it seemed unnecessary. I did not feel that it was necessary, and at, as one member told me, an estimated cost to the NHS of £1000 per review I assumed that the Department of Health would agree with me. From my reading of the governance there are three aspects of this research which potentially raise ethical problems. Firstly, my research project does include both a questionnaire survey to some NHS staff and in-depth interviews with them. However, as I am not myself a member of NHS staff I have no relationship with potential informants that might lead to undue pressure for them to participate. It could be argued that the NHS, as their employer, has a duty to act as a gate-keeper regarding the types of research that its staff can be recruited for. It seems to me though that this is not an argument that is particularly persuasive. I don't, for example, think that we would consider this an acceptable argument to make concerning a private employer. The involvement of NHS staff in this research does not therefore raise any additional ethical questions.

The second issue raised by the Governance is that of adequate information being provided to potential informants, so as to ensure an 'informed consent' to taking part in the research. When I approached one committee chair to see if it would be possible to approach members for interview I was told that I would have to produce an information sheet in line with NHS guidelines. In itself this was a worthwhile process, in part because it gave me experience of the researcher's perspective in the ethical review, but primarily because it is good research practice (and probably something that I should have done without being asked). What I found interesting though was more that it was an obligatory passage point. I am not sure how important what I said in my information sheet was, but that I had written it and in the standard format obviously was. Once I had produced the sheet the committee were put at ease and incredibly helpful and interested. However, I feel that because of the nature of this research and these informants the primary risk in not providing enough information is a problem of recruitment rather than of any exploitation.

The other ethical issues raised by the NHS Governance are those of confidentiality of data and anonymity of informants in any work that it produced

using these data. In line with standard social science practices I discussed with participants what taking part would entail and put our agreement in writing for them. These exchanges were temporal and local. My feeling that there was no need for an ethical review of my 'procedure' and, moreover, that such a review could not guarantee ethical practice, which depended on my integrity as a researcher, was precipitated by the fact that I was not dealing with 'vulnerable groups'. The feelings also betray a 'prejudice' I had as I began the research. We do not enter the field as 'blank slates' but must, as researchers, be prepared to have our prejudices challenged.

Map of the thesis

In chapters two and four I develop the methodology of this research, what I call emplaced bioethics. I argue that, rather than assuming that applying bioethical principles is a straightforward matter, we need to pay careful attention to the spaces in which bioethical problems arise and are addressed. I begin the thesis with a discussion of academic Bioethics, a discipline that has emerged to answer exactly the kinds of questions that LRECs address in the course of their review of medical research. Bioethics uses the tools of analytic philosophy to answer questions in the abstract. I outline a number of approaches within the discipline; principlism, communitarianism, narrative Bioethics, and empirical Bioethics. I argue that these schools of thought all have in common an emphasis on reason as the warrant of debate, the aim to provide prescriptions, and a fore-fronting of revelation of the universals 'hidden' in the particulars of each problem. I argue that this insistence impoverishes understanding of the bioethical issues arising from medicine and bio-science.

In chapter three I provide an historical background and regulatory context for the in-depth discussion that follows. I describe the historical development of LRECs and the increasingly binding Governance that they work under (this shows that these issues have become more pressing) and the survey. In chapter four I begin outlining a counter analysis of bioethical issues. I argue we need to make a distinction between, Bioethics, the academic subject and bioethics, the

ethical issues arising from bio-science and medical technologies. I describe LRECs and their emplaced bioethical reasoning. In chapters five to eight, I describe four issues that are key to understanding LRECs: the science-ethics dichotomy, informed consent, locality, and lay involvement on committees. I end this thesis by reflecting on LRECs and the notion of emplaced ethics more generally. I describe how this research, with its emphasis on emplaced bioethical understanding, challenges current policymaking.

Chapter 2

The view from the Bioethicist's office

> It is the existence of a common and neutral moral language, independent of contextualised social relationships, capable of mediating ethical dilemmas in the diversity of social sites where biomedicine unfolds which is contested by ethnographically minded critics. (Lopez, 2004: 878)

Introduction

Over the last half-century or so, rather like a virulent effect of technological progress, Bioethics has spread rapidly (Van Loon, 2002, Jonsen, 1998). Bioethics uses the tools of analytic philosophy to address the ethical implications of bioscience, biotechnology, and medicine generally. As Lopez, quoted above, suggests, Bioethics posits these problems as pertaining to acontextual universals, Bioethicists promise a disinterested analysis of what ought to be done in any such situation. Such claims to neutral and objective analysis, though, ought to make us suspicious. There are no views from nowhere (Haraway, 1991). Rather, Bioethics offers one view, is one perspective, as partial and power laden as any other. It is a view from the Bioethicist's office.

In this thesis I make a distinction between Bioethics and bioethics. Capitalised, Bioethics refers to a formal (primarily) academic discipline and the modes of reasoning and warrant accepted within that discipline. However, bioethics refers more generally to the ethical issues arising from bio- science and technology and medicine. These issues may, or may not, be explicitly called bioethical issues in the places in which they occur and are resolved. They may not even be encountered as problems in need of resolution. The scope of bioethics extends further than that of the Bioethicists' office, to parliaments,

hospital wards, operating theatres, doctors' offices, medical conferences, and beyond. The focus of this thesis is one such space of bioethics, Local Research Ethics Committees. Academics and policy makers assume Bioethics can be taken and 'applied' in practice, such as in LREC deliberation. As my analysis shows, the actors in this site are very reticent to call their deliberations Bioethics though. In order to understand this reaction, and indeed offer an alternative to 'applied' Bioethics, I turn to the practice of LRECs. In this chapter I describe Bioethics and outline some key debates within the discipline in order to, in the next chapter, offer a counter analysis.

In this chapter I review a number of pertinent debates in the Bioethics literature and consider what role geographies of bioethics can serve. I begin by asking what Bioethics is, a subject that is contested, often with vitriol. I then outline the orthodox school of Bioethics, principlism and its often unintended emphasis on informed consent. Principlism has been much attacked but remains, perhaps because of its apparent simplicity, the conventional Bioethics approach. I describe, though, the main schools of Bioethics that critique principlism. I end this chapter with a discussion of how geography could inform Bioethics, in particular, how space and spatial relations are fundamental to understanding the ethical issues arising in bioscience and medicine. The schools of Bioethics I describe, with their disregard for space and place, will serve as a backdrop for the counter-analysis I develop in the rest of the thesis.

What is Bioethics?

> Bioethics is the study of the moral and social implications of techniques resulting from advances in the biological sciences. (Warnock, 1995; 93)

On its website The Nuffield Council of Bioethics asks 'What is Bioethics?' It gives a long and varied list of potential areas for Bioethical investigation:

> Genetic testing and screening, reproductive and therapeutic cloning, the use of stem cells, embryo research, abortion, assisted reproduction, prenatal screening, end-of-life issues including euthanasia, the use of human tissue, organ donation, xenotransplanation, the use of animals in research, genetically modified crops, research with human subjects, the ethics of research related to healthcare in developing countries, patenting DNA, pharmacogenetics, patient confidentiality, resource allocation.
>
> (Nuffield Council on Bioethics, 2004)

Bioethics often concerns the types of science described on the Nuffield website; ground breaking, controversial, and morally contentious. True, some of these issues, such as research on animals for example, do not concern this kind of big science, directly at least. Some of the other issues, such as resource allocation, are older ones that have been transformed by modern science. For the most part though the subject matter of Bioethics is prompted by science fiction-like advances. These are, it seems, new types of moral questions. As the Nuffield's answer to its own question goes on:

> It is sometimes said that science moves so quickly that ethics has difficulty in keeping up. Just because something is technically possible does not mean that it should be done. It is crucial that ethical, legal and social issues raised by the introduction of a new technology are considered from an early stage. By bringing together ethical analysis and scientific understanding, society can evaluate policies and regulate developments. (Nuffield Council on Bioethics, 2004)

One of the emerging consequences of bioscience is the ability to transform and enhance life. This power to manipulate the world brings with it confusing and morally problematic possibilities. The hybridity of what science produces challenges us to think about what it means to be human, when life begins and ends, and about what is natural. In the face of such questions Bioethics offers a sure footing.

In order to address these issues, Bioethics uses the tools of analytical philosophy to provide conceptual and normative analysis to answer the question: what ought to be done? Bioethics is, in the words of Fox, 'a highly rational, formal, largely deductive mode of argumentation' (quoted in Hedgecoe, 2004: 124). For example, given advances in technology and medicine, the point at which babies born pre-maturely can survive with the assistance of machines is changing. Does this alteration of the viability of human life have, as many argue, implications for the morally acceptability of abortion, and if so, how? Bioethics aims to provide an answer to questions like this one and to develop general theory concerning how such issues can be resolved (Beauchamp and Childress, 1994, Levine, 1988, Beauchamp and Walters, 1994). Its conceptual analysis involves examining the logical validity of arguments, the consequences of such arguments, and the appropriateness of categorisations. For example, in the case of abortion we have to ask: does physical viability inform our concept of personhood, and if so, with what moral implication for people who are indefinitely kept alive artificially? The aim of Bioethics is to produce an analysis of what actions and decisions ought to be made in such circumstances.

Increasingly, Bioethicists are leaving their offices and engaging with policy makers and health care practitioners (Lewens, 2004b, Bailey, 2001, Lillehammer, 2004). We are seeing the emergence of Bioethicists *qua* experts. For example, as I describe in chapter four, academic Bioethicists sit on LRECs and all members receive formal training in Bioethical frameworks. A number of arguments have been levelled at the role Bioethicists are increasingly playing (De Vries, 2004). Bioethics has accepted the interpretations of modernist medicine as privileged, beyond scrutiny, and thus failed to fulfil its obligations to patients themselves and wider society (Loewy and Loewy, 2001, Brody, 1997, Irving and Hallowell, 2004). In particular, some argue it has been guilty of framing its subject matter as pertaining to the technically innovative and theoretically interesting rather than the socially pressing. These tend to be the sort of headline grabbing technological breakthroughs, like Dolly the sheep, described above. Bioethicists tend to have much less to say about (literally) crippling poverty (Holmes, 2001, Shaw et al., 1999).

The Philosophers' lament

It has become a concern for philosophers that work undertaken in the name of Bioethics is often less than robust in its application of analytic philosophical standards than it should be (Lewens, 2004b, O'Neill, 2002). As the social and ethical problems resulting from advances in science and technology become more pressing, Bioethicists are called on to converse with those outside their own discipline, with the media, politicians, and health care practitioners (Lewens, 2004a, Rachels, 1999). It is no surprise to some that the demanding discipline of philosophy proper has been 'less marketable than the corrupted version of "ethics", which offers spurious "guidance" to both besieged practitioners and to policy-makers hungry for an ethical rationale for their preferred policies' (Loughlin, 2004: 75).

Although there have always been publicly well known philosophers - Bertrand Russell and Mary Warnock spring to mind - the systematic inclusion of Bioethics into policy and decision-making is a recent development. Does philosophy have anything to offer? Won't it be changed in the process?

> The starting point for these questions is the observation that bioethicists are not confined to lecture theatres and seminar rooms. On both sides of the Atlantic, they have roles in the formulation of policy, in deciding particular medical cases in hospitals, and in advising corporations and charities. It is these phenomena that raise questions of usefulness and corruption. First, do bioethicists have anything valuable to offer in these practical areas? Second, are there reasons to think that engagement with non-academic institutions of various kinds might cause bioethicists to lose their integrity, or that bioethics as a discipline might come to serve a dubious function. (Lewens, 2004b: 122)

Indeed, Bioethics is changing as a result of its new role. Bioethicists increasingly might draw on legal precedent, professional standards, and the general cultural milieu to answer questions (Kuczewski, 1997). In this, some argue, Bioethical investigation has been lost to other subjects that 'can only characterized as ill disciplined' Harris (2001: 4).

In particular, Harris (2001, , 2004) argues, two wrong-headed things have started to happen in Bioethics, first, the implication of Bioethics in the policy-making arena and secondly, the appearance of empirical investigations of what ought to be studied analytically.

The inclusion of the needs of policy-making in 'up-stream' bioethical reasoning (what Harris calls its 'globalization'), with its emphasis on public opinion and consensus, has changed the nature of Bioethics. Harris comments:

> The globalization of bioethics may be thought of as the phenomenon according to which the ethical agenda is increasingly set, not by religious, cultural, and indeed ethical traditions, nor by competition in the market place of ideas, nor by community leaders, exceptional sages, or 'saints', nor indeed moral philosophers but rather in a new and unprecedented way. This agenda is now set by national and international ethics committees, or committees with ethical agendas, and by the conventions, protocols, reports, or conclusions which they produce, and which are disseminated either by the bodies and governments to whom these bodies report or increasingly, by the press and media interest they arouse. (Harris, 2001: 5)

The demands now being made on the discipline of Bioethics by policy and practice, by what we might call 'states of the world', change the nature of the discipline. In particular, the need to converse with those outside the discipline, outside the academy even, changes the warrant of the subject. Where once the citation of an abstract and obscure point of philosophy or a rigorous logical analysis would have served as justification, it no longer will. In response, Harris calls for what we might describe as a purification of the subject. Whilst, on the whole his characterisation of the turn in Bioethics is fair, his conclusion is unappealing. His imagined past where 'community leaders' and 'sages', or, for that matter, moral philosophers set ethical agendas is not one I want to go back (or indeed forward) to.

A further crime committed in the name of Bioethics, for Harris, is the inclusion of empirical methods to answer these sorts of questions. People calling

themselves Bioethicists use surveys and the like to answer bioethical questions. To the philosopher, at least, it seems clear that normative issues need to be studied conceptually rather than empirically. There is a logical distinction to be made between what is, and what ought to be. Returning to the example of abortion, the point at which people do have abortions has nothing to tell us about the point at which people ought/ought not to have abortions. Social science might have a role to play in establishing certain facts for the philosopher to use in his/her analysis. Just as no Bioethicist worth his salt would get his natural science wrong, there are certain things he might also need to know about society (Hedgecoe, 2004). This, though, is a preliminary data gathering that happens before analysis proper.

Harris (2001) argues that the inappropriate rise of empirical methods in Bioethics has developed due to pressure from the need for an easily recognised and understood methodology. Philosophical 'methods' do not lend themselves well to the peer review research funding process (p13-14). I share his criticism of much empirical Bioethics and laud his commitment to understanding academic disciplines as socio-political achievements. In chapter seven I will argue, as Harris does, that public participation in (LRECs') ethical decision-making, while near universally accepted, is inchoate and thus potentially damaging. However, what I cannot agree with is his call for the purification of Bioethics. In actual fact, it is precisely by the espousal of a 'view from nowhere' that analytic philosophy has enabled the 'globalisation' of Bioethics that so troubles Harris. To answer the ethical issues arising from bioscience and medicine, we need to become less 'pure', and more embedded in the messy lived reality of those issues. This is not an approach Bioethicists welcome.

Side-stepping these disciplinary boundary skirmishes between Bioethics and philosophy proper, I want to argue that there are characteristics that unite Bioethics as a discourse. The first characteristic is that Bioethics presumes the ethical issues arising from bioscience and technology are amenable to reason. Second, Bioethics sets itself the task of producing prescriptive pronouncements. Taken together, these two characteristics mean Bioethicists use reasoned arguments to provide 'answers' to ethical problems. Next, Bioethics addresses

ethical issues but not the contexts in which these issues arise. In other words, Bioethics has a universalistic underpinning: Bioethics can 'reveal' the real ethical problems hidden by the particularities. It can provide answers, but it is not the role of Bioethics to implement or 're-particularise' their answers. Finally, Bioethics is taken to be an area of expertise (Lillehammer, 2004, Loughlin, 2004, Irving and Hallowell, 2004). The Oxford English Dictionary describes an expert as, 'one whose special knowledge or skill causes him (sic) to be regarded as an authority'. In a sense this explains the previous point. Bioethicists do not need to get involved with the beliefs, desires, and actions of those embroiled in the situations they discuss, as the methods they have mastery of 'solve' the moral problems. This is only a broad-brush sketch of Bioethics and one that, no doubt, many would want to challenge. However, the differences ought not distract us from the similarities within Bioethics.

The four principles of Bioethics: Principlism

Principlism has come to be the most orthodox of all schools of Bioethics. Beauchamp and Childress' *Principles of bioethical medicine* was first published in 1979. In it they set out the four principles approach to Bioethics, what has become known as principlism. A cluster of four principles, Beauchamp and Childress argue, serve as an analytic framework for 'identifying and reflecting on moral problems' (2001: 15). The principles, that ought to always be promoted, are respect for autonomy, beneficence, non-maleficence, and justice. These principles are self evident and universal. They serve as a foundation for all ethical deliberation. In Lopez's (2004) words, principlism seems to offer a common and neutral language.

Principlism adapts easily to policy and practice. Its 'top down' reasoning and adoption of liberal legal notions have contributed to principlism being codified in statements of ethics and regulation (Levine, 1988). Its stress on respect for autonomy responds to a particular historical need for a professional ethics that rejects the 'doctor knows best' paternalism of old (Hogg, 1999, May and Mead, 1999, Rothman, 2001) and deals with, or more precisely, perhaps, is seen to deal with, past abuses of patients and research subjects (Annas and

Grodin, 1992, Lock, 1995). Furthermore, the principles of beneficence and non maleficence mirror doctors' Hippocratic codes (Edelstein, 1943). Principlism seems, then, to serve multiple needs facing an ethical framework.

One consequence that has become increasingly apparent in the operationalisation of principlism is the dominance of a single principle. Beauchamp and Childress (2001: 57) describe the principle of respect for a person's autonomy as being 'as deep in common morality as any principle'. Others have described it as a basic human need (Doyal and Gough, 1991) and as what makes us human (Foster, 1997). While Beauchamp and Childress dispute that one principle should have precedence, respect for autonomy has become 'the 'default' principle of applied principlism, the principle to be appealed to when principles conflict' (Lopez, 2002, Irving and Hallowell, 2004).

Moreover, this 'default' principle has been further reduced to one particular conceptualisation, that of informed consent. Requiring an informed consent from patients undergoing treatment or participants in medical research depends on that person: (1) knowing what is involved, (2) facing neither internal nor external coercion, and (3) then, and only then, agreeing. In law, the definition of informed consent provides a mechanism for prosecuting those who have infringed the rights of another individual. Based in tort law, it can take the form of an action of battery or of negligence. Faden and Beauchamp (1986) suggest that the best understanding of the legal entity 'informed consent' is as an effective consent requiring that the patient has adequate information, is competent to understand this information, is free from external constraints or coercions and decides to consent. [For an in depth discussion of the development of these elements through case law see Kennedy & Grubb (2000)].

Bioethicists argue that ethically informed consent carries more exacting requirements than are found in the law (Brazier, 1992, Faden and Beauchamp, 1986, Katz, 1993, Katz, 1984, MacLean, 2000, Meisel and Kuczewski, 1996, Wear, 1999). The (ethical) importance of informed consent to research is most often articulated as arising from the deontological primacy of persons (Meisel and Kuczewski, 1996, Doyal and Tobias, 2001, Faden and Beauchamp, 1986,

Jones, 1995, Newman, 1996, Sharpe, 2000, Titus and Keane, 1996). In probably its most famous statement Kant argued that we must treat other people as ends and not means (Tauber, 2001, Secker, 1999). Set in such an ethical framework, informed consent according to Faden and Beauchamp (1986) is best understood as 'an autonomous authorization' by a patient to a proposed medical procedure. Ethicists often dismiss the moral value of the legal doctrine (Katz, 1993, Brazier, 1992, Faden and Beauchamp, 1986, Wear, 1999, MacLean, 2000, Schneider, 1994). Brazier (1992), for example, argues that the legal understanding of effective consent pays little more than lip service to ethical understandings of the value of patient autonomy. There is, though, an ever-present danger of principlism doing little more than reasserting legal doctrine.

Culture, community, and technology: Communitarian critiques of principlism and beyond

An important strand of argument against principlism expands the criticism that principlism's notion of Bioethics does little more than reinforce legal rights. These critiques dispute the concept of personhood enshrined in principlism. A number of arguments are made here. I begin by describing the communitarian argument, which emphasises the relational construction of each person.

Communitarian critics argue that persons are not the essentially atomistic entities posited by principlism, with its emphasis on informed consent (Turner, 2003). Certainly, from certain cultural and ethical perspectives this emphasis on individual consent is of questionable value. Requiring informed consent from a patient necessitates informing the patient about all possible outcomes of a procedure. Such information is not always welcome. For instance, Navajo beliefs about the power of speech to shape the future means that information about possible adverse outcomes is not readily welcomed (Cecire et al., 2000). Other belief systems, such as those that enshrine the importance of the family in

protecting the sick from bad news, may also reject the liberal individualism on which informed consent is based (Kuczewski, 1996).

Such accounts of cultural practices are welcome as they begin to expose the perspectives hidden in principlism's 'self evident' values. However, we need to proceed cautiously for communities, like persons, are neither unitary, essentialist, nor transparent. The community of communitarian ethics is, most often, a rather abstract or metaphoric entity, devoid, most troublingly, of politics. If we are to include such concepts as cultural communities in our moral reasoning we need to be cautious about who gets to act as spokesperson for these communities.

Other theorists concern themselves not so much with the primacy of culture per se but with other types of community. These may be pre-existing communities, or particular relations entered into when one becomes a patient or when one encounters significant life events such as birth, disability, and death. Communitarian ethicists have rejected understandings of informed consent that enshrine "individualistic and legalistic assumptions" (Kuczewski, 1996: 31). Instead they argue patient autonomy should be thought of as the result of a process of engagement with significant others and indeed with medical staff:

> The individualistic conception of self makes sense of the doctrine of informed consent in terms of the patient's civil rights....Bioethicists writing in a communitarian vein have challenged this vision of the person. When working in a clinical setting it is clear that persons are not self-sufficient entities. One's values are not necessarily mysterious things developed privately, and they are seldomly completely subjective or arbitrary. (Kuczewski and McCruden, 2001: 3, cf. Hester, 1998)

For such communitarian Bioethicists, autonomy must be the end, the goal, of the informed consent process, not simply its precondition. Other theorists have argued respect for persons ought to take other forms than informed consent. Barilan and Weintraub (2001), for example, argue persuasion to make the right decision, rather than eliciting an informed consent, is the proper way for

clinicians to respect persons. Certainly, the importance of the effect of communication between doctors and patients needs to be taken into account. Appropriate communication may be necessary for protecting patient autonomy (Katz, 1984), but it is untenable to argue fundamental conflicts of values can be reduced to failures of communication (Jones, 1995).

A related area of criticism foregrounds the embodiment of persons. Contrary to the Enlightenment conception of person with its implicit mind-body dualism, these critics argue embodiment must be accounted for in ethics. Feminist ethicists, for example, have argued that men and women experience morality differently. Accordingly, they have developed the notion of an ethic of care (Gilligan, 1997, Held, 1997, Friedman, 1997, Mahowald, 2001). Without perhaps wanting to re-write ethics in this way, other theorists critique princiciplism's informed consent as both racist and sexist (Myser, 2003, Corrigan, 2002, Messikomer et al., 2001).

Acknowledgement of embodiment in ethical debate introduces an engagement with our more than human ways of being. For it is not only our 'natural' embodiment, but also technology, that constructs human subjectivity (Rose, 2001). Many of the ethical questions Bioethics seeks to address feature a hybridity brought about by an enhancement of humanness through chemicals or technologies. Principlism, which seeks to address this hybridity by re-inscribing Enlightenment ideals of mind-body dualism, it is argued, will always be found wanting (Castree et al., 2004).

Certainly, principlism's notion of personhood is refined. It conceptualises people as rational, self-knowing, and independent. As many writers have acknowledged, we need to challenge such understandings and the ethics on which they are based (Chrysanthou, 2002, Popke, 2003). What is interesting for the purposes of this thesis is the way in which these schools of thought envisage ethics as relational and constructive. One of the key roles of LRECs, I will argue, concerns informed consent. If we take on board the schools of thought discussed here then we see that LRECs are implicated in constructing ethical subjectivities.

Narrative Bioethics

An alternative strand of criticism centres not on the nature of personhood per se, but on the nature of moral reasoning, and in its stronger versions, on being-in-the-world. In its obsession with forensic logic and proposition-like maxims principlism fails to make sense of bioethical issues, the narrative Bioethicist argues, because it fails to take account of what moral reasoning is actually like. Narrative Bioethics is interesting because it begins to question the universal basis of Bioethics and move towards more hermeneutic understandings of the world. In this section I describe the genesis of narrative Bioethics and some possible positions that have been taken in its name.

Narrative Bioethics is one element in a wider 'personal turn' in moral philosophy (Williams, 1995). The new-found interest in Aristotle's concept of ethics as a practical knowledge gives credence to the requirement to take everyday-ways-of-knowing seriously (Kuczewski and Polansky, 2002). As with feminist 'ethics of care', narrative Bioethics attempts to describe a normative ethical theory more reminiscent of how people experience moral decision-making. Universal ethical theory and its demand to treat people impartially neither resembles everyday ethical deliberations as we live them nor does it provide convincing reasons for people to behave in certain ways (Williams, 1981), for it is not logically valid arguments that convince people to behave in the right way. As Takala (2004: 73) argues:

> Unluckily for philosophers, many people seem to be quite content to hold incoherent views on ethical issues, and it is very difficult to argue that their approach is somehow decisively inferior to the insistence on coherence. If ethics is believed to involve something more profound than rational arguments, this belief cannot really be shaken by rational arguments.

Rather than a rational problem-solving guided by logic and coherence, everyday decision making is more likely to be about muddling through and compromising between different and sometimes irreconcilable demands (Hoffmaster, 1992).

Narrative Bioethics foregrounds the phenomenological experience of ethics. Although a huge variety of claims sit under the label 'narrative Bioethics', all agree that moral meaning comes not from law-like universals but from narrative structure. Whereas communitarian ethicists argue for an ethics based on a different ontology (a claim that can be supported either empirically or metaphysically), narrative Bioethics requires theorists to engage with the people's moral world. In practice, this can be a very rarefied moral world, for example, that of 'great literature' (Nussbaum, 1990). Narrative Bioethics, though, holds stories as fundamental to our moral experience. To experience something as a moral problem, to deliberate about the right course of action and come to a decision, does not occur, it is claimed, because we have mastered the appropriate rules or have knowledge of a series of propositions (Murray, 1997: 8-9). Instead, everyday ethical deliberations 'either naturally take narrative form or must be given narrative structure if they are to have moral meaning' (Nelson, 1997: ix). In other words, there must be a story for there to be a moral of the story.

Whilst stories are obviously part of our initiation into moral communities (think also of the fairytales we are told as children), narrative Bioethicists make the further claim that narrative structure is the mode of rationality through which ethical meaning is understood and communicated. Stories here are not just thought of as 'carriers' of moral truths, but constitutive of them (Murray, 1997). It follows that if principlists do not think they are storytellers they are wrong. Kuczewski (1997; 137), for example, argues Bioethics, as a distinctive branch of ethics, involves an implicit assumption that 'there is a skilful way to construct the case such that its salient features will become thematic, and acceptable resolutions will surface'.

Murray (1997), identifies a four-fold typology of the uses of narratives in Bioethics, which although incomplete is broadly helpful. First, from the observation that storytelling plays a fundamental role in our induction into a moral community (as right thinking/feeling members of that community) ethicists then look to use stories to further educate us as individuals and as a

moral community (Murray, 1997 pp.6-7). Stories are 'vivid illustrations of knowledge verified through other means' (Tomlinson, 1997: 125).This mode of narrative Bioethics might include analysis of films and novels in order to both reveal what makes actions right and to develop the skills of empathy and reflection described as being essential to behaving ethically (Charon, 1997, Weijer, 1997, Nussbaum, 1990). Stories, it is argued (Montello, 1997, Nixon, 1997), can be usefully employed in teaching health professionals about ethics. In other words, along with training in clinical practice and scientific rationality, doctors must be trained to make sound ethical decisions. Using stories and narrative analysis is one way to do this.

Murray's second mode of narrative Bioethics uses narratives as what he calls a methodology. He includes here casuistry, or case based reasoning, where problematic 'cases' are compared by analogy with 'paradigm cases' that are thought to exhibit more clearly a right course of action. Similarly, his third mode recognises that narratives are fundamental to making moral sense of the world and from that, I assume, it follows that including narratives as a style of writing in academic ethics is seen as right and proper. Murray calls this mode, 'narrative as appropriate moral discourse'. Finally, narratives can be thought of as moral justifications, as 'what gives us confidence in our moral judgements' (Murray, 1997:13). This seems a rather confused category including both personal identity narratives and understandings of truth as historically contingent and hermeneutic.

In order to constitute a defensible position, the general claim that narrative structure is central to normative theory, must be developed. In particular, two questions must be answered. The first concerns what normative theory in narrative Bioethics looks like. Working with narratives, Nelson (1997: viii) says, allows philosophers to work up-close to their material: 'to put faces on faceless generalizations, to take the particulars of a given situation carefully into account'. What practices does narrative Bioethics involve, though, and what should Bioethicists 'output' look like? Having claimed everyday ethics is important, do narrative Bioethicists need to go 'out into the world' and collect stories to be used as 'data', or is it permissible to remain office-bound and write their own narratives? The second question Bioethicists are charged with concerns

what sorts of truth claims are being made: how does narrative Bioethics defend itself against the charge of relativism? What is its warrant? In the 'plague of stories' being visited on Bioethics, many feel the connection between narrative and moral justification remains 'maddeningly obscure' (Arras, 1997). Bioethicists still need to take their pronouncements and 'defend them from mere prejudice' (Williams, 1995: 550). Without foundation in universals, narrative Bioethics leads to relativism (Macklin, 1999, Arras, 1997).

While the question of relativism perplexes the universally minded, another (far more interesting) question is posed. The question that must follow for narrative Bioethics concerns the relationship between narrative Bioethics and everyday narrative ethics. Having accepted the validity of everyday moral reasoning, in mode if not content, what then for the Bioethicist as expert?

Murray's final classification of narrative Bioethics involves narratives replacing universals as the foundation of truth. Murray's illustration is vague and clouded in metaphors, its metaphysics and epistemology underdeveloped. There is, though, a rich history of continental philosophy and social science epistemology that could be used to develop an non-mimetic epistemology of Bioethics (Demeritt and Dyer, 2002). One important conception of narratives that is adopted in social science is an emancipatory one. Thus an alternative conception of narrative in Bioethics, neglected by Murray, is as a framework for giving 'voice' to patients and their carers. Stories are calls for recognition because they forefront the authenticity of the storyteller rather than the Truth of the story (Stanley, 1994, Dhana, 1994). In such a conception, the Bioethicists' stories are secondary.

Narrative Bioethics, however underdeveloped, present us with an alternative conception of warrant in Bioethics. We might well ask if we are going to forefront the lived reality of ethical decision making then why not do it for real and use empirical evidence with these hermeneutic epistemologies?

Empirical bioethics

As Harris (2004) so antagonistically points out, people calling themselves Bioethicists have begun to engage with the ethical questions arising from bioscience and technology using empirical methods. This practice threatens the 'purity' of Bioethics as applied philosophy. An important distinction needs to be made, philosophers argue, between prescriptive and descriptive statements. What actually is the case, will never furnish us with answers about what should be the case: there is no 'ought' from an 'is' (Hume, 1975, Harris, 2001).

Empirical Bioethicists reply though that without analysis of what is, as well as what ought to be, Bioethics stands little chance of even getting the questions right let alone coming up with the right answers. What biomedical issues are ethically problematic and need addressing is a matters of fact rather than logic (Holm, 2004). Moreover, in order to address properly whatever issues are pertinent, a Bioethicist needs to be properly informed. Describing the responsibilities of academic philosophers, Nussbaum (1998: 765) argues:

> But philosophy cannot do its job well unless it is informed by fact and experience: that is why the philosopher, while neither field-worker nor politician, should try to get close to the reality she describes.

However, what such an engagement means is hotly contested.

A number of explanations exist for the emergence of empirical Bioethics. Harris (2001) describes changes to funding of university research as pivotal. Philosophical analysis, he argues, is not amenable to anticipatory peer review. Borry *et al* (2005) see the trend emerging from the rise of evidence-based paradigm in medicine and policy. Bioethicists' involvement in these arenas has influenced their practices and thus the warrant of Bioethics. With different emphases both Harris (2001, , 2004) and Ashcroft (2003) suggest empirical Bioethics, first and foremost, serves the needs of policy makers:

> ...precisely because such research methods (survey and semi structured interviews), in the policy arena, are intended not as decision-making for a for democratic political practice, but as means for knowledge production and the foreclosure of policy debates, the apparent commitment to giving a voice to the voiceless, and hearing the authentic voice of the powerless is mere mystification. (Ashcroft, 2003: 9)

Empirical Bioethics, on this reading, serves as a kind of market research that prescinds proper ethical consideration.

There are many types of empirical research being used to address bioethical issues, and such 'market research' is no doubt one. However, the existence of 'good' empirical Bioethics (reflexive, challenging, rigorous) is unlikely to convince the philosopher as it begs the question. It assumes there can be such a thing as good empirical Bioethics. Holm (2004), though, using conceptual analysis argues 'ought' implies 'can'. There is no moral obligation, he argues, to perform an action that is a physical impossibility for me. Moreover, limitations on human agency are not only physical, they are sometimes psychological or social. Thus:

> ...for the opponent who accepts that in certain circumstances the fact that I cannot perform an act entails that I have no moral obligation to perform it is left with the more difficult position to explain what kind of 'cannot' implies which kind of 'no obligation'. (Holm, 2004: 7)

If the answer is that there are some social or psychological 'cannots' that are relevant, then it is only through empirical research that these can be investigated.

Whatever the theoretical grounding of empirical Bioethics, it is increasingly common (Holm and Irving, 2004). The forms these empirical studies take are numerous. Methodologies range from small ethnographic studies to surveys and textual analysis. Studies may seek to elucidate public attitudes, through surveys, focus groups, or media analysis (Ashcroft, 2003, Andrew Irving Associates, 2002, Levitt, 2003). Other studies address the understanding and ethical concerns

of patients or health professionals (Featherstone and Donovan, 1998, Mason and Allmark, 2000). Often these studies measure practice against theory. In other words, 'compliance' with the ethical standards espoused by Bioethicists (Sugarman et al., 1999). Certainly, researchers always need to be critically attuned to the politics of the arenas they are researching and ask themselves whose need their research is serving (Loewy and Loewy, 2001, Ashcroft, 2004).

Much empirical research investigating bioethical issues does not call itself Bioethics, but sociology or anthropology (or geography). For example, there is sociological work on the hidden politics of best practice (Molewijk et al., 2003, Timmermans and Berg, 2003) and priority setting (Martin and Singer, 2003). In her exploration of the decision by American women to take amniocentesis tests and then what course of action to take when tests showed Spina Bifida or Down syndrome affected a foetus, Rapp (2000) showed that women applied very different ethical frameworks to the decisions they had to take than the Bioethicists who addressed the same problem theoretically. This is empirical research on bioethical issues, par excellence. However, Rapp does not call herself a Bioethicist, and if we return to the question, 'what is Bioethics?', her work does not meet the criteria. Rapp does not position herself as an expert in ethics nor does she give prescriptions for what decisions, she thinks, people should make. Rather, she uses empirical research to illuminate the difficult, contextualised ethically problematic situations people find themselves in and the paths they find through to an 'answer'.

Geographies of (bio)ethics

Bioethics, the academic discipline and the modes of reasoning it uses, has a geography. In his history of Bioethics, Jonsen (1998: 377) argues that although Bioethics originates and has developed in the USA it is now a 'worldwide phenomenon'. Such declarations, while remaining essentially meaningless without proper empirical investigation, demonstrate at the very least the subject's imperialist tendencies. Whilst the academic field named Bioethics remained,

until recently, primarily a North American one, Jonsen (1998) is right to suggest its modes and tropes of reasoning are beginning to become more widespread.

Bioethics certainly has an interesting geography that is yet to be told. Where acceptance of Bioethics is occurring and with what effects are questions ripe for (geographically sensitive) research. Research currently being undertaken does promise to begin to piece together such a geography. The GENDEP project at the LSE's BIOS centre is using retrospective document analysis to investigate the ethical review of a piece of genetic research across Europe (BIOS, 2005), while a study based at Sussex is using ethnographic methods to elucidate the working practices of research ethics committees in UK, Sweden, Portugal, and Hungary (Hedgecoe, 2005). These studies of the macro-geographies of Bioethics and Bioethical regulation recognise that the implementation of standardised protocols is an activity requiring professional judgement in which many factors, including national cultures and histories, are at play.

Moreover, there is much geography implicit in Bioethics: 'local', 'distant others', 'moral community', and so on. Despite what has been called a 'personal turn' in ethics, and the plethora of spatial metaphors it displays, Bioethics remains socially and spatially naïve (Sayer and Storper, 1997). Many Bioethicists' recent considerations, such as community (Loewy and Loewy, 2001, Cecire et al., 2000) and distance (Benatar, 2002), are ideas to which geographers have much to contribute. The blurring of the boundary between humans and nature, and between what is given and what is malleable, lies at the heart of much Bioethics. Again, this human-nature dichotomy is one that geographers are well practiced in traversing creatively (Castree et al., 2004). Geography may well be able to provide a fruitful interlocutor for a dialogue about how empirical investigations can generate a more placed and situated means of ethical decision making.

In 'abstracting away' the spaces in which bioethical deliberation occurs, both their own (their offices) and the situations they study, Bioethicists reify moral problems as pertaining to universals. The study of bioethical issues needs to be spatialised. Bioethics needs to take notice of the spatial distribution of

resources (and thus the spatial distribution of injustice[1]), an issue with obvious relevance in health care. It needs to re-examine 'community' and 'person' not as analytic categories but as things that are found in the world. Bioethics has, on the whole, ignored such issues to its detriment. Most of all Bioethicists need to 'un-abstract' themselves.

Conclusion

Bioethics purports to be objective, rational, universal: a 'view from nowhere'. We must re-focus this claim by thinking of Bioethics as a social practice. Academic Bioethics, like all knowledge production, has methods, warrants, and framing practices, all of which can be contested. The aim of this chapter has not been to produce a sociology of Bioethics, but to position Academic Bioethics as only one way of addressing the ethical issues arising from bioscience and medicine. I have described some of the broad schools of Bioethics. The rise of the Bioethicist as expert, to be called in to settle issues, needs to be vigorously examined.

In the rest of this thesis I turn to a counter analysis of bioethical issues, a geography of bioethics. Geography is concerned with how where things happen makes a difference. As Smith (1999: 20) argues, 'the nature of actual human relationships mediated by distance is crucial to the development of moral values'. Such an observation is important to understanding, and thus better addressing, bioethical issues as part of the spaces in which they occur.

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[1] An argument reminiscent of the philosophical problem of moral luck (Nagel 1979).

Chapter 3

Local Research Ethics Committees: Their History and Current Governance

Introduction

Local Research Ethics Committees (LRECs) exist to review medical research involving human subjects. In the course of their review of applications they are involved in bioethical discussions of the ethical issues arising from the use of humans within research. In order to understand these bioethical discussions we must first understand the context in which LRECs operate.

LRECs have existed in one form or another in the UK since the 1960s. The committees consist of between ten and twenty members who meet once a month to review applications. The majority of committee members are health professionals, doctors, nurses or pharmacists, or have some expertise relevant to medical research, such as statisticians. Committees also have a couple of lay members whose role I explore in chapter eight. Health authorities[2] host committees although the committees are, strictly speaking, independent of the NHS. Researchers who want to conduct research within a health authority using NHS staff, patients, or premises must have prior research ethics committee approval.

In this chapter I describe the historical development of LRECs. I begin by describing the emergence of prototype committees. I outline the increasing volume of guidelines and progressively tighter governance, culminating in the

[2] Health Authorities have taken a number of organisational guises over the period I am discussing. I refer simply to health authorities.

current legally binding Governance. Issued in July 2001 these latest Governance Arrangements for Research Ethics Committees (Department of Health, 2001a)[3] are aimed at standardising LREC practice and constitution across the UK. I describe, using others' research on LRECs, committees past operating practices. Finally, using the results of a questionnaire survey, I describe LRECs as they existed and operated during the period of my fieldwork. This gives a context for the rest of the thesis, which, using more in-depth qualitative research methods, describes LRECs and how they practice bioethical decision-making.

The rise of self-regulation

The history of LRECs in the UK has been marked by an organic evolution. Following the Second World War the ethics of medical research appeared on the agenda of the international community. The atrocities committed, in the name of medical research, in Nazi concentration camps gave rise to the Nuremberg Code (1946) of medical research ethics (Annas and Grodin, 1992). In the UK that code was not backed by much government involvement or formalised systems until well into the 1980s. Research ethics were seen as professional matters, best dealt with by doctors. As Salter argues, self-regulation has advantages for governments as well as the professionals themselves.

> [The State] does not wish to assume direct responsibility for the governance of medicine since it, rather than the medical profession would then become the immediate target for citizen discontent...The advantage of self-regulation to the state is the distance it puts between itself and its citizens. (Salter, 2000: 41-42)

From the 1960 onwards ethical review has been marked by such self-regulation. This self-regulation has, though, has become increasingly mediated by the demands of government and industry.

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[3] The governance arrangements are often referred to by members as GAfREC. In this thesis I refer to the document as the Governance. It is referenced once at the beginning of each chapter.

Prototype ethics committees

In 1967, following the lead of the United States, a fellow of the Royal College of Physicians called for the establishment of committees in medical school, hospitals, and research institutions to provide independent review of research involving human subjects. The Surgeon-General of the United States Public Health Service had published a statement on the responsibility of institutions for such a review, which was then ratified in federal law (Foster, 1997). In an open letter to the president of The Royal College, Dr. Desmond Laurence argued for similar committees to be established in the UK. The Royal College responded by commissioning its 'Supervision of Ethics of Clinical Trial Investigations in Institutions' guidance (Royal College of Physicians, 1967). The government department responsible for the NHS, the Ministry of Health, sent a letter to the boards of governors of all hospitals endorsing the Royal College's guidance (Foster, 1998, Ministry of Health, 1968). These guidelines established an expectation, rather than (as in the US) a formal statutory requirement for review of the ethics of research conducted at the level of the institution. The form this took was professional self-regulation, of doctors by doctors.

The establishment of prototype LRECs was part of a more general change of attitude towards research participants. Of course, it is not possible to divine the private opinions of members of the research community. However, what it was publicly permissible to espouse was changing. In the 1963 Marc Daniel lecture, Sir Austin Bradford Hill argued that the regulation of ethics was an impossibility as the particularities of clinical medicine cannot be foreseen. He argued that regulation undermines and discounts doctors' professional expertise. He took particular affront at the requirement to elicit an informed consent from research participants, arguing that requiring informed consent from patients is unworkable: a patient is unlikely to fully understand the condition and 'give his (sic) *understanding* consent to his (sic) inclusion in a trial…(and) *that nothing less is of value*' (quoted in the *British Medical Journal* Editorial, 1963). The times were changing though, and his lecture was not well received. The Chair of The Patients' Association argued in *The Times* that patients should be told about

trials they were being entered into and that 'it begs the question to say that it is difficult to explain these things to ignorant and sick people' (Hodgson, 1963). The *British Medical Journal* agreed:

> We ourselves are in no doubt that in their enthusiasm for knowledge some medical men (sic), and their co-experimenters, have gone too far. That is why guidance had become not only desirable but imperative, in the form of a code of ethics - this time drawn up by doctors. (Editorial, 1963: 5349)

In an example of exactly the kind of self regulation the *BMJ* called for, a year later the Medical Research Council (MRC) published guidelines for researchers using human subjects (Medical Research Council, 1964). A year later the World Medical Association published its own guidelines (World Medical Association, 1964).

At around the same time as the Royal College published its guidelines for research ethics committees, two doctors, one in the USA and one in the UK, collected evidence of wide spread neglect of ethics in medical research (Beecher, 1966, Pappworth, 1967). Modern debates about such ethics had their genesis in the war crimes tried at Nuremberg (Lock, 1995, Annas and Grodin, 1992). These articles by Pappworth and Beecher refocused the tenor of debate. In the abuses they uncovered, the perpetrators were not evil war criminals but fellow professionals whose actions were, probably with the best intentions, unacceptable abuses of patients.

Government involvement

In 1975, the UK government published its own guidance on the ethical review of research (Department of Health and Social Security, 1975). It was not until 1991, however, that ethics committees were formally established in the Health Service Circular HSG(91)5 (Department of Health, 1991), which stipulated that health authorities must set up LRECs but the instruction had no statutory force. Then, in 1997, a second tier of research ethics committees, known as Multi-Centre Research Ethics Committees (MRECs), were established

to review research taking place over multiple sites (Department of Health, 1997). From 1975 onwards, then, the self-regulation of LRECs was mediated by guidance from central government. Both the 1991 and 1997 guidelines were non-statutory although NHS employees were required to submit research for ethical review as part of their employment contract (Neuberger, 1992, Holley and Foster, 1998).

This lack of formal guidance by government reflected a wider faith in professional self-regulation. Statements of ethics written explicitly for medical researchers were produced both nationally and internationally by organisations such as the World Medical Association, the MRC, and the Royal Colleges. Presumably this advice, written by professional bodies for researchers, was used by LRECs in assessing the ethical merits of the applications submitted to them. Now, however, there is an enormous volume of literature produced to advise REC members, which is collated into a Manual by the Centre for Medical and Legal Ethics (Foster, 1997).

The system of LRECs, which had evolved piecemeal, was increasingly seen to be failing. A number of scandals concerning the ethics of medical research in the UK focused the government's attention on ethical review. In North Staffordshire hospital, premature babies died in the 1990s while participating in research that had been approved by an LREC. In the aftermath of events, parents said they had not consented to their children taking part in research (Dyer, 2001, NHS Executive West Midlands Regional Office, 2000). The LREC system also proved unable able to prevent the infamous 'harvesting' of organs of dead children for research at Alder Hey hospital (Hunter, 2001), while the LREC that approved research, published in 1998, claiming a link between MMR and autism, came under intense criticism for allowing that research to go ahead (Dyer, 2004). Moreover, the letters pages of the medical press were also full of complaints from researchers. As I describe below, the system did not serve their needs. It was slow, idiosyncratic, and unaccountable. The development of a global medical research market required an internationally 'harmonised' system of ethical review (Abraham and Reed, 2002, , 2003). If

Britain was to host medical research, the system for ethical review would need to be reformed.

The irregularity of practice

Given the organic development of the system of ethical review of medical research it is perhaps unsurprising that LRECs existed in many forms. Another consequence is the lack of systematic data and relatively few formal records documenting their past function and practice. In this section I sketch out debates about the irregularity of practice in broad terms and then turn to what research exists to elucidate past practice. In turn, I look at LRECs membership, their systems of accountability and their meetings and approvals. I argue in the period until 1997 LRECs were marked by this irregularity. It was in 1997, with the establishment of MRECs, that the Department of Health started to seriously address the standardisation of ethical review.

Until the second tier of the REC system was established in 1997, researchers had to apply separately to each and every LREC in the areas where they wished to conduct research. If researchers were to undertake a nationwide research study they would have to apply to each of the 200 odd LRECs in Britain. Most of these committees had different application forms and, in researchers' experience, it was common for them to request different amendments (Harries et al., 1994, Kent, 1999). For researchers it was the lack of uniformity, both in the application process and in the decisions reached, that were vexing. As one clinical researcher complained in the correspondence pages of the *British Medical Journal*:

> Can it really be that a trial quickly and unreservedly considered ethical at Land's End and elsewhere is unethical, or only marginally ethical, in John O'Groats? (Meade, 1990: 395)

The author answers his own rhetorical question, condemning the REC system at that time as 'cumbersome, confusing, and frustrating to the point of being unworkable.' (Meade, 1990).

Evidence from the letters pages of medical journals makes it clear that the time REC review took was a big issue for researchers. Little empirical research, though, was done on how long it took LRECs to reach a decision (Foster and Holley, 1998, Thompson et al., 1981). A questionnaire survey (of 97 researchers) suggested in the late 1990s some researchers were receiving approval within days whilst other were waiting up to 175 days [the longest time reported was a year and a half (Foster and Holley, 1998)]. Researchers, with the support of the powerful pharmaceutical industry, argued that they needed a quicker and more predictable review if they were to undertake research in the UK.

In the face of these criticisms, some still maintained that LRECs provided a review that was pragmatic and sensitive to the local needs of the researchers and participant communities (Foster, 1998). Whilst not disagreeing with the need for standard procedures, there were voices insisting that different committees often had legitimate reasons for reaching different conclusions about some research protocols. 'Rather like religion, ethics can evoke strong convictions' afforded one rationalisation in the *BMJ* (Editorial, 1997). Foster (1995), editor of the *Manual for Research Ethics Committees* in the 1990s, made the point more forensically: by applying different moral frameworks to the same problem, ethics committees might quite legitimately reach different decisions. Indeed, such arguments, about the inevitability of variation in LREC decision-making are still being made (Edwards et al., 2004). These arguments, though, did not carry much weight with the first director of the Central Office for Research Ethics Committees, Terry Stacey (1998), who argued that a standard review was not only possible but essential.

The membership of LRECs

In the period to 2000 the size of the committees varied considerably. Whether or not the standardising of the size of LRECs was essential to

standardising their decision-making is a mute point. However, the standardisation of committee size has been a topic of interest for government and researchers alike. A survey of thirty-four Scottish LRECs in 1981 found that committees had between one and 73 members. The majority, though, had seven or fewer full voting members (62%) (Thompson et al., 1981). Doctors dominated committees. 34% of the committees had no nurse members, but 68% of committees had at least one 'lay' member. The majority of these lay members were non-medical NHS employees (56%).

Nationwide research, a decade later, examined compliance with the 1991 Department of Health guidelines for committees to have eight to 12 members (Department of Health, 1991, Neuberger, 1992). This King's Fund study found 24% of committees surveyed had too few members and 19% had too many. In other words, nearly half of committees did not meet the guidelines. Committees were, it found, predominantly male, with 28% of committees having fewer than 1 in 5 women members. Furthermore, 34 % of committees had less than the two lay members advised; nearly a third of lay members were either clergy (14%) or lawyers (16%) (Neuberger, 1992). A few years later, another survey found that compliance concerning committee size had improved slightly (with 54% of committees meeting the requirement) (Foster et al., 1995). Compliance, concerning lay membership, though, had improved with all committees having at least one lay member, and only 5% having just one. However, clergy and lawyers remained a sizable proportion of the lay membership: 32 % of committees had a clergyman as a member and 21% had a lawyer. 59% of committees met the requirement of a lay person in the role of either chair or vice-chair. An analysis of all annual reports produced in the years 1996- 2000 found that compliance with the 1991 requirement had remained reasonably stable. In these years, for the committees that produced annual reports, the percentage of committees with between eight and 12 members remained within the range 45-54%. The mean number of lay members on committee remained in the range 2.6-2.8 members (Godfrey et al., 2001). There seems to have been much variation around the country. A 1998 survey of the South Thames region, for example, found that 78% of committees were of the recommended size, which implies that compliance in other regions must have been much less, if the national average

was only about 50% (Holley and Foster, 1998). The problem of compliance with the 1991 guidelines may well have been a function of the practical difficulties of having such a small committee. If a member could not attend a meeting, the actual numbers at any meeting would be extremely small. The 2001 Governance addressed this problem by increasing the maximum committee size from 12 to 18.

With all this focus on the easily measurable (and auditable) question of committee size, very little has been written about the appointment of members to LRECs. The Royal College of Physicians' 1990 guidelines suggested that committees themselves might want to propose people to health authorities for consideration. In Scotland in the early 1980s appointment methods varied between committees, including membership ex officio, nomination and election (Thompson et al., 1981). Neuberger (1992) found that there was no standard appointment procedure, appointments being made by the health authority or by election.

Public reporting

The 1991 guidelines instructed LRECs that they should produce an annual report. Again, many committees failed to comply with this stipulation. In 1992, only 15% of Neuberger's sample of 28 committees with which she conducted in-depth research produced an annual report, while another 21% were in the process of starting to produce one in line with Department of Health 1991 guidelines. Though it produced an annual report one committee refused to publish the names of its committee members. In the mid 1990s 38% of committees still published reports giving no information about any of the protocols they had reviewed (Foster et al., 1995) and sparse information about who sat on the committees (Foster et al., 1995, Godfrey et al., 2001).

Meetings and approvals

At the beginning of the 1980s the number of meetings committees held varied hugely. The Scottish survey revealed a variety of working practices

(Thompson et al., 1981). Only 6% of Scottish RECs surveyed had held 10 or more meetings in the previous year, whilst 38% had not met at all in the previous year. Of these, 50% reported that they conducted their business without meetings while 26% had not considered a research protocol in the previous 12 months. Only a third of all committees surveyed had a standard procedure for the submission of research protocols. Committees also reported variation in the time taken for consideration of protocols, from less than a month (50%) to within 3 months (the other 50%). Of the 370 applications that had been considered by committees in the previous year, 7 had been rejected outright, 53 were returned for modification (of which 46 were resubmitted and all but one was accepted), and therefore 310, that is 84%, had been passed without modification. Thompson et al (1981) concluded that there was an uncertainty from the RECs as to what their remit was . Of the 34 committees, 35% felt that they entirely, and 56% that they largely, satisfied the maintenance of proper ethical standards in research. The survey asked what ethical issues they had encountered in applications. They answered: risk to subject: 75%; consent: 71%; Drug trials: 32%; confidentiality: 25%; coercion to subjects: 32%; respect for life: 14%; others 29%; no problems: 15%.

It is difficult to know how representative Allen and Water (1982) were, however, they undertook a ten year retrospective study of one committee, which found both a rise in the number of applications submitted and a rise in the number requiring modification (from 10% in 1971 to 41% in 1981). The types of modifications requested changed too. There was, they reported, a gradual change from committees finding researchers' choice of subject unsatisfactory to problems with the information provided to subjects. Allen and Water conclude that this was due to a change of attitude of the LREC rather than a change of protocols, although, they also noted a change to the subjects covered in applications to LRECs. In 1971 no mention was made of discomfort, inconvenience, or harm to the subject, whereas by 1979 nearly half of applications did.

Throughout the 1980s and well into the 1990s, the number of meetings held and applications reviewed by LRECs exhibited great variation.

Nevertheless, there was a general increase in the number of applications being reviewed, though some committees had so few applications as to warrant only three meetings a year (Neuberger, 1992), while other committees reviewed 311 protocols in a year (Smith et al., 1997b) (the same number of protocols Thomas et al (1981) report 34 committees seeing in one year). In their review of LREC annual reports, Foster et al. (1995) found some committees reviewing as many as 351 applications a year. This, though, was unusual; most committees (41%) reviewed less than 50 protocols, 20% between 50 and 100, and only 9% between 100 and 200. The number of meetings in which these applications were reviewed varied too: 34% of committees had six or less meetings a year, and 10% had twelve or more.

With the establishment of the MREC tier of review in 1997, we might have expected the number of protocols reviewed by LRECs to fall. Although there is limited evidence, this does not seem to have been the case. Godfrey et al (2001) report that in the period 1996 to 1999 the average number of applications reviewed per LREC meeting only fell from 10.9 to 9.9. These figures, though, conceal a wide range, from around two applications reviewed in a meeting to as many as 40. In this same time period the mean number of meetings seemed to remain constant (between 9.5-10 per year, with a range of three to the mid twenties) (Godfrey et al., 2001). A more limited survey of 27 committees in the South Thames region found a mean of 8.1 meetings a year (Holley and Foster, 1998).

Very little analysis has been conducted on the decision making of LRECs. Research in 1997 surveyed committee members, patients, and researchers for their views about the role of the committee (Kent, 1997). Committee members were found to be most concerned with the protection of subjects' rights whilst, patients and researchers thought that they should be most concerned with protecting against harm. Kent (1999) found that there was a great variety in the type of modification requested by the four committees he studied. The mean percentage of applications reviewed requiring requests for modification was 24% (with a range of 6% to 32% by individual committees). Of these the majority were amendments to information sheets (57%), a pattern I

explore in more detail in chapter six. A separate analysis of application forms and guidance to researchers found that all committees mentioned information to subjects as being a criterion. They also all mentioned 12 other issues, including suitability of the researcher, consent, and safety (Holley and Foster, 1998).

In the light of such variation in the practices of LRECs, the problems this caused for researchers and the sponsors of their research, it became clear that such informal self regulation would have to be replaced with another system.

Standardising LREC review

In 2000 the Department of Health set up the Central Office of Research Ethics Committees (COREC) to run MRECs directly and provide support for LRECs (Central Office for Research Ethics Committees, 2002b). In July 2001, the Department of Health published new Governance for RECs as part of a wider national Research Governance Framework for Health and Social Care (Department of Health, 2001b) . This Governance signalled a real shift in the history of LRECs, and it is therefore worth going into some detail about its requirements. In the rest of the thesis I argue that LRECs should still be thought of as a mechanism of self-regulation. The Governance, though, sets out more tight parameters for the operation of this professional self-regulation.

The need to address irregularity of practice came in response not only to complaints from the British research community but also from international pressures to facilitate global research and development; the pharmaceutical industry had been pressuring national regulators to co-ordinate their requirements for developing, testing, and licence. One result of this was the International Conference on Harmonisation (ICH) which brought together regulators from Europe, Japan, and USA and pharmaceutical company experts, with the aim of harmonising ethical review.

> The objective of such harmonisation is a more economical use of human, animal and material resources, and the elimination of unnecessary delay in

> the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), 2005).

In 1996 the ICH published its document outlining the role research ethics committees should play (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), 1996). Medical research has become globalised:

> A major concern was to secure quality in the ethical review process of multicentre, transnational clinical trials for pivotal studies. As the methodology of pharmaceutical research becomes increasingly transnational, with science sharing everywhere the same quest, a central challenge was to perceive how the ethical review process could – in the global environment of science – address the universal dignity of the human person in the specific expression of national, regional and local cultural situations (Crawley and Hoet, 1997; 122)

Thus the ethical review of that research had also to be globalised. This required standardisation of the sort outlined in the Governance.

The Governance was published in July 2001. This coincided with the EU publishing European Directive 2001/20/EC (The European Parliament, 2001/21/EC), which required member states to have standard operating procedures for RECs by 2003. In April 2004 the Medicine for Human Use (Clinical Trial) Regulation 2004 went before parliament and came into force on 1st May 2004 (2004). RECs were thus established in British law.

The Governance set out the constitution and appointment procedures for RECs. Health Authorities are accountable for the establishment, support, training and monitoring of all LRECs that review research undertaken in the NHS (3.5). Health Authorities must ensure that enough LRECs have been established to

cope with the workload (4.8). Although research may take place at several locations, LREC 'approval' is only required from one LREC within each Health Authority (3.5). All other LRECs are then bound by this decision.

Membership of LRECs

The Governance increases the maximum size of committees, but restricts who can sit on a LREC as a lay member. LRECs should have a maximum of 18 members with a quorum being seven (6.1, 6.11)[4]. If less than seven members attend a meeting then no decisions can be made. Membership of LRECs should have 'a broad range of experience and expertise, so that the scientific, clinical and methodological aspects of a research proposal can be reconciled with the welfare of the research participants, and with broader ethical implications' (6.1). Membership should be of balanced age and gender distribution, with efforts made to recruit people from ethnic minority backgrounds and people with disabilities. LRECs are committees made up of at least one third of "lay" members, who are defined as being independent of the NHS, and whose primary personal or professional interest is not in a research area (6.5). Additionally, at least half of those members defined as "lay" must 'not be nor have been, either health or social care professionals, or be involved in carrying out research involving human participants, their tissue or data'. (5.7). Whilst it is clear that lay members are not supposed to be doctors or nurses, there is no statement in the Governance about what positive characteristics or skills lay members are supposed to have. The vagueness of the role lay members in the Governance forms the starting point of chapter eight, in which I examine the contested constructions of 'layness' in the ethical review of medical research. Appointment of members must be 'by an open process' according to the Nolan Standards and must be laid down in Standard Operating procedures (5.3). Again, though, there are no stated criteria by which applicants should be judged. Members should be appointed for fixed terms, normally five years, which may be renewed, but not more than twice on the same REC (5.2).

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[4] All such numbers refer to the Governance 2001.

Public reporting

The Governance lays out the responsibilities of committee members as well as the committee as a whole. Once appointed, members must have initial and continuing training in 'research ethics, research methodology and research governance' (4.10). They are expected to maintain confidentiality (6.7) and must attend two thirds of meetings each year (5.5). Each Health Authority has liability for mistakes committee members make in good faith (4.14). Members are appointed in their own right and are not representatives of any group (6.8, 7.17). Committees need to be able to demonstrate that they have 'acted reasonably in reaching a particular decision' (7.9). Decisions must be available to the public (7.18) and an annual report detailing the constitution and activities of the committee must be produced (7.20). The REC must make known to the researcher any additional progress reports that it requires in addition to the annual report from the researcher stipulated in the Governance (7.27, 7.31).

Meetings and approval criteria

The Governance states that once a valid application has been received a decision must be reached and communicated to the applicant within 60 days (7.10). There must be enough research ethics committees in each Health Authority to ensure this is the case. The review should be in parallel with other reviews that must be undertaken, for example by NHS Research and Development Committees or Medicine Control Agency (7.15).

LRECs' primary task is the ethical review of research proposals and their supporting documents, 'with special attention given to the nature of any intervention and its safety for participants, to the informed consent process, documentation, and to the suitability and feasibility of the protocol' (9.7). LRECs must operate within the Governance framework, which is determined by the Department of Health. However, its review must be independent 'from political, institutional, profession-related or market influences' (2.5). LRECs should ask first what serves the interest of the potential research subject and 'concerned communities' (2.3). Best interest is construed as being the 'dignity, rights, safety, and well being' (2.3). The 'interests, needs and safety' of potential researchers

are important but secondary. Review must also involve considerations of 'the principle of justice', which is defined as a concern that the 'benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account in particular age, gender, economic status, culture and ethnic considerations' (2.4).

The Governance identifies the following issues for consideration in any review as involving: ensuring there has been a scientific review of design and conduct of the study (9.13), recruitment of subjects (9.14), care and protection of research participants (9.15), protection of research participants' confidentiality (9.16), informed consent process (9.17), and community considerations (9.18).

In the case of research subjected to MREC ethical review, LRECs are only responsible for reviewing any 'locality issue' (8.3, 8.9). Locality issues are formally defined as: 1) the suitability of the local researcher, 2) the appropriateness of the local research environment and facilities, and 3) specific issues relating to the local community, including the need for provision of information in languages other than English (8.8). Despite this guidance, the question of the ethical significance of locality issues remains a constant one, as I discuss in chapter seven.

Given the past irregularity of practice, implementation of the Governance required LRECs to make huge changes to meet these standards. The timing of my fieldwork coincided with this period of adjustment by LRECs. In order to make an assessment about how well LRECs were making the changes I undertook a questionnaire survey to which I now turn.

Current practice

Questionnaires were sent in November 2002 to all 215 LRECs listed on the COREC website (see appendices nine and 10). This was over a year after the Governance had first been published and around eight months after all

committees should have been operating according to it. All of the information in the following section comes from that survey.

Membership

The membership of committees ranged from seven to 21 members, with the majority of committees having between 10 and 15 members (figure 3.1). Only 9% have more than the 18 members prescribed by the Governance. LRECs reported having between one and eight lay members, with the majority of committees having two, three, or four lay members (25%, 29%, 24% respectively). One of the committees that took part in the in-depth phase of my research had reported in the questionnaire that it had only one lay member. By the time I observed the meeting some months later, though, it had recruited additional lay members. That may be common, with it taking committees a while to recruit lay members to meet the Governance stipulation. Unsurprisingly, larger committees have more lay members (12% of LRECs have more than six lay members, all but one of these committees have more than 16 members in total.) The requirement for either the chair or vice chair to be a lay member was removed during the period of the fieldwork. However, 25% of committees had a lay chair and 41% had a lay vice chair.

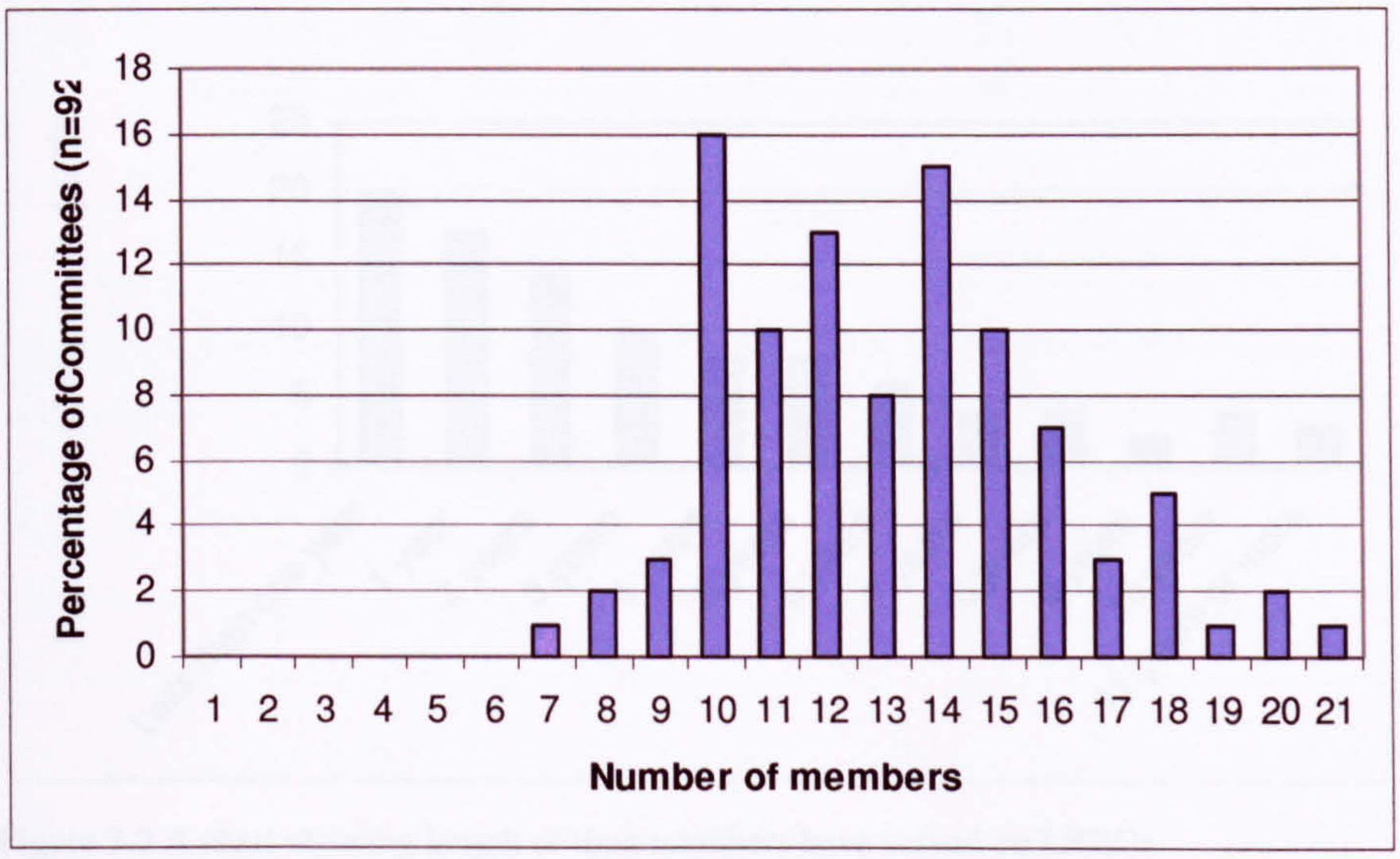

Figure 3.1 A chart showing the size of LRECs

The Governance requires LRECs to have adequate expertise to review research. Most committees had one or two nurse members (57% and 35% respectively), one or two general practitioners (GPs) (55% and 19% respectively) and a pharmacist (77%), although rather a lot of committees had no GP member (20%), no pharmacist member (15%) or no statistician (63%). The Governance requires recruitment that is balanced in terms of age and gender, with efforts to be made to recruit members from ethnic minorities. 55% percent of committee members are men and 91% are ethnically white (6% being Asian and 1% Black). Of the lay membership, 54% are women, 95% are white. 37% of lay members reported that their highest degree was a first degree and 41% said it was a higher degree. The compares with just 16% of the general working population having a first or higher degree (The Office of National Statistics, 2003).

Twenty percent of members had joined their committees in the previous year (figure 3.2). Given the timing of the survey, this is to be expected. To comply with the Governance most LRECs had to expend their membership. The majority of members had received some training, although only a few days (figure 3.3). LREC administrators, though, had been receiving training about how LRECs should operate (figure 3.4).

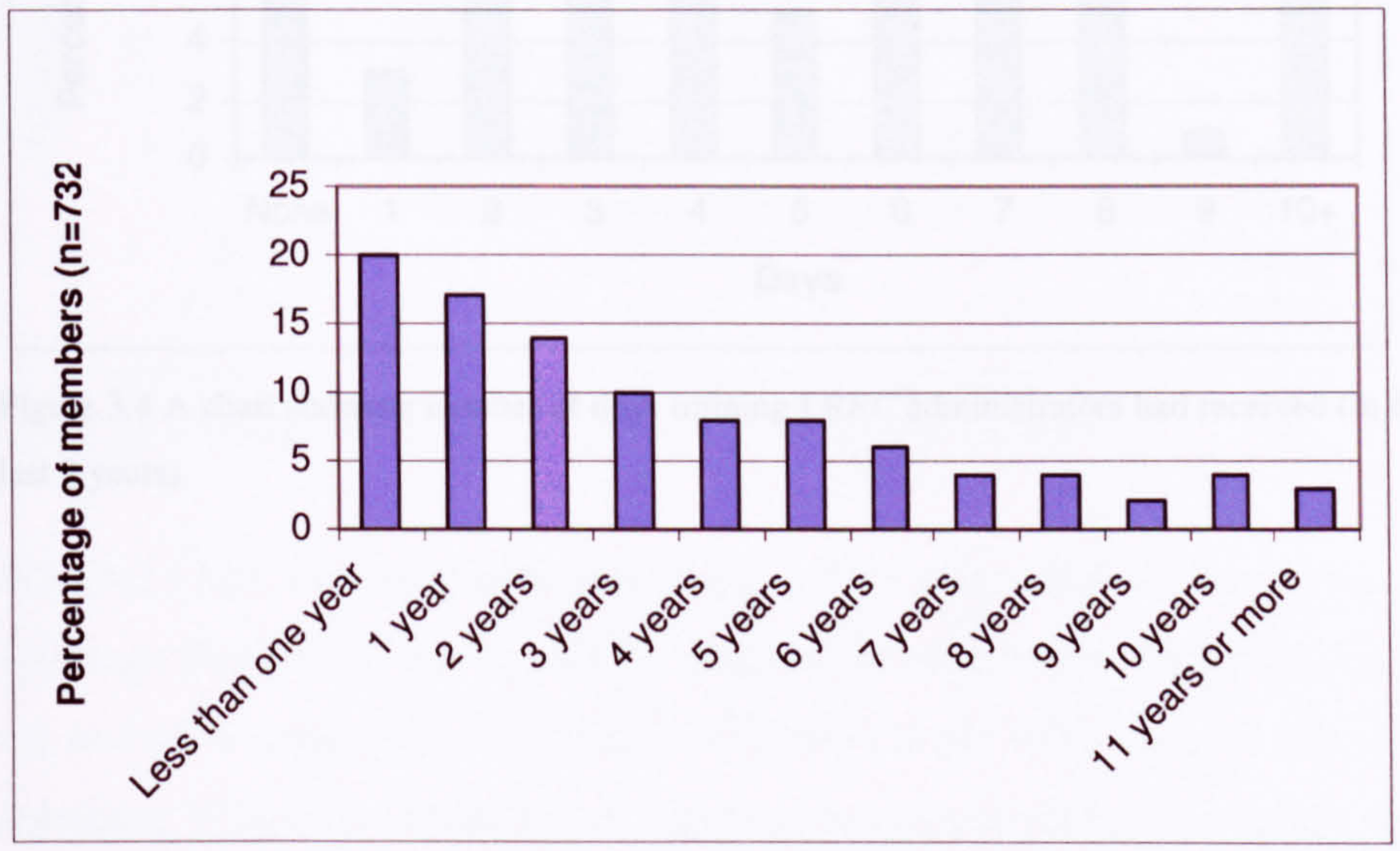

Figure 3.2 A chart showing length of time members have served on LRECs

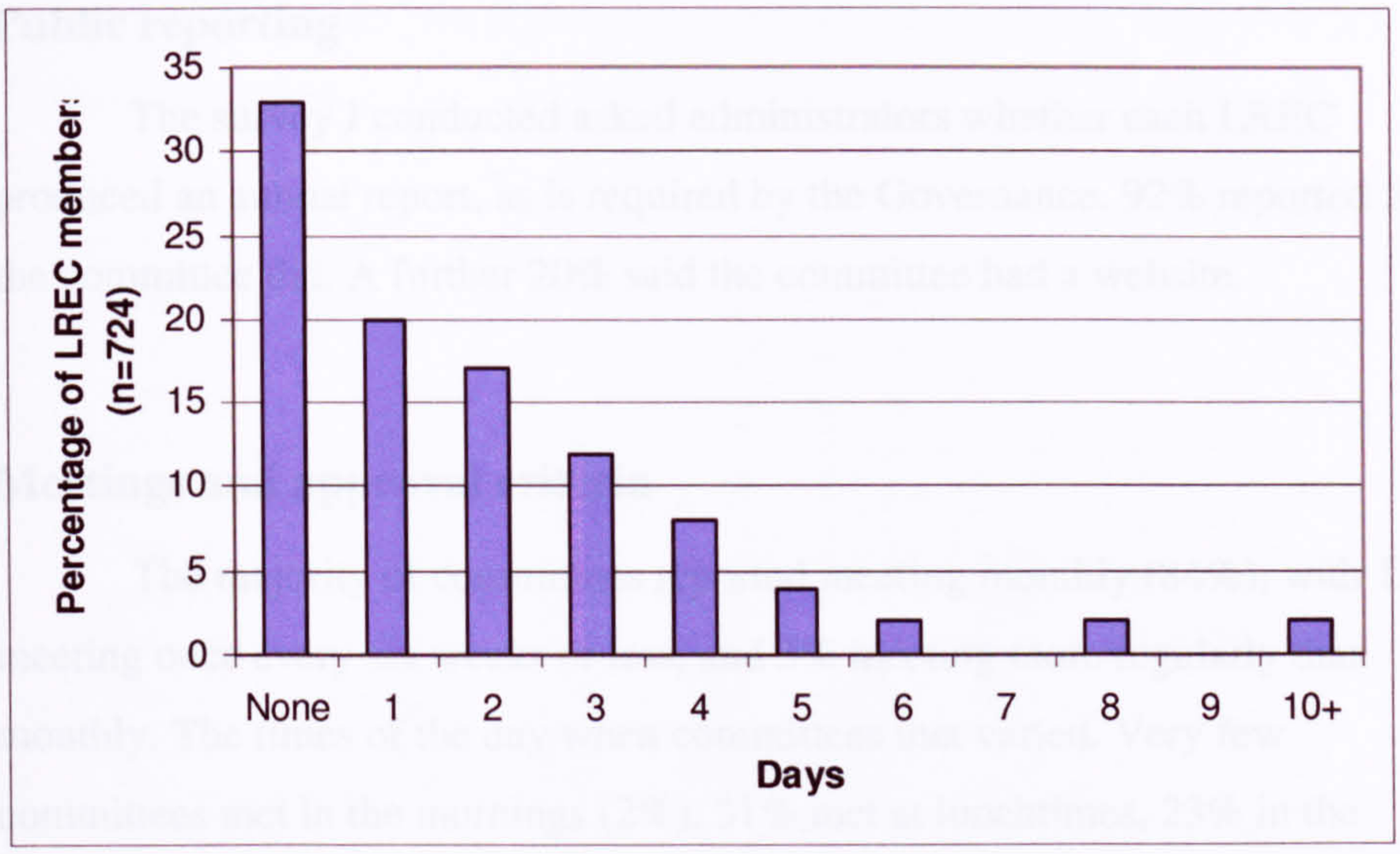

Figure 3.3 A chart showing number of days training LREC members have received (in the last two years)

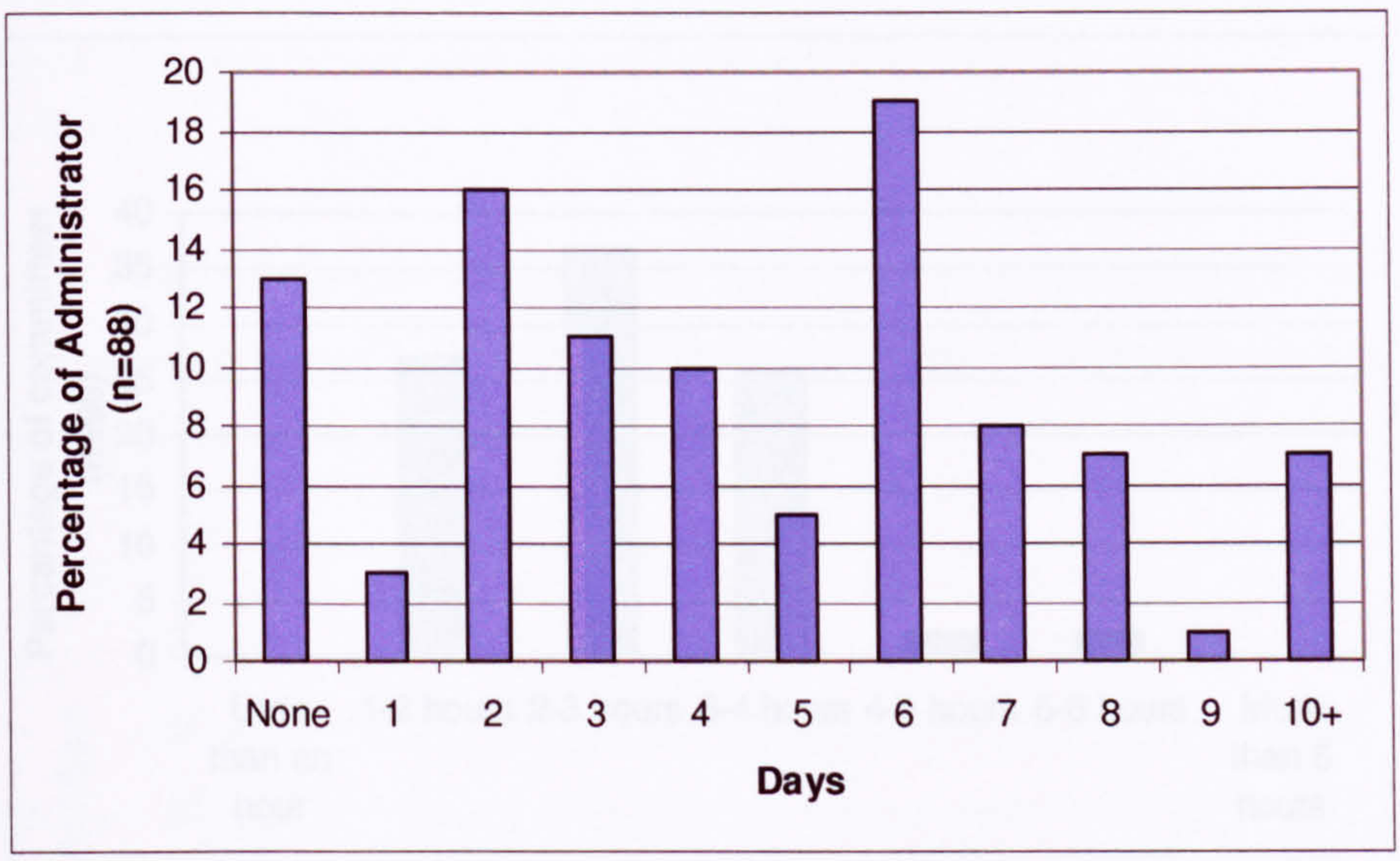

Figure 3.4 A chart showing number of days training LREC administrators had received (in the last 2 years)

Public reporting

The survey I conducted asked administrators whether each LREC produced an annual report, as is required by the Governance. 92% reported that the committee did. A further 20% said the committee had a website.

Meetings and approval criteria

The majority of committees reported meeting monthly (84%), with 13% meeting once every six weeks or less, and 3% meeting more regularly than monthly. The times of the day when committees met varied. Very few committees met in the mornings (2%). 31% met at lunchtimes, 23% in the afternoon, and 30% in the evening. There was, though, a huge range in the length of LREC meetings (figure 3.4).

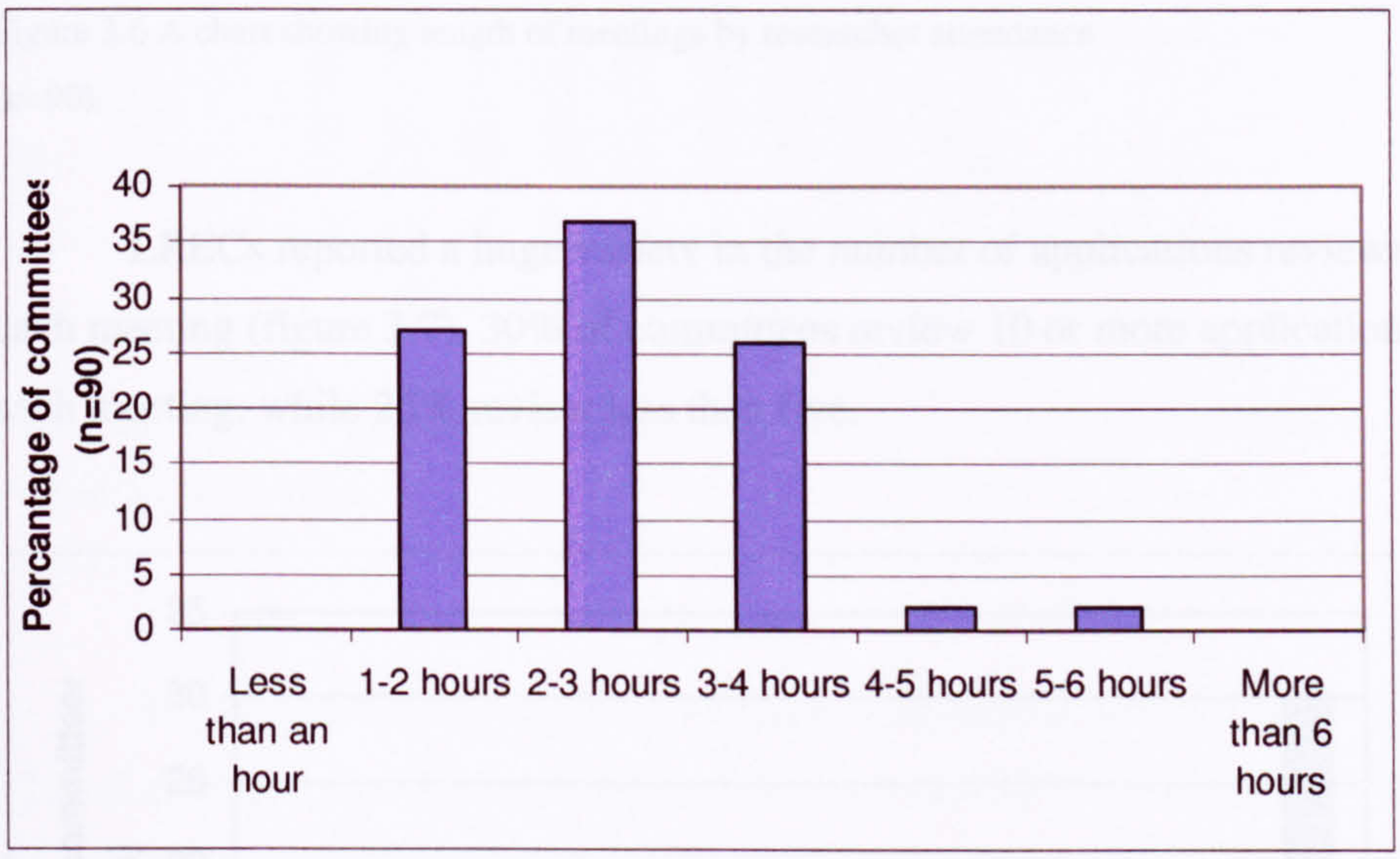

Figure 3.5 A chart showing the length of LREC meetings (last 3 months)

Whether LRECs invite researchers seems to have some effect on the length of meetings (figure 3.6). 5% of LRECs never invite researchers, 48% occasionally do, and 46 % usually do. No committees always invite researchers to attend meetings. With committees whose meetings last five to six hours, though, the relationship changes. Whether this is because of the small sample of these

committees (only two committees), or their general 'outlying' behaviour, or both, it is impossible to say.

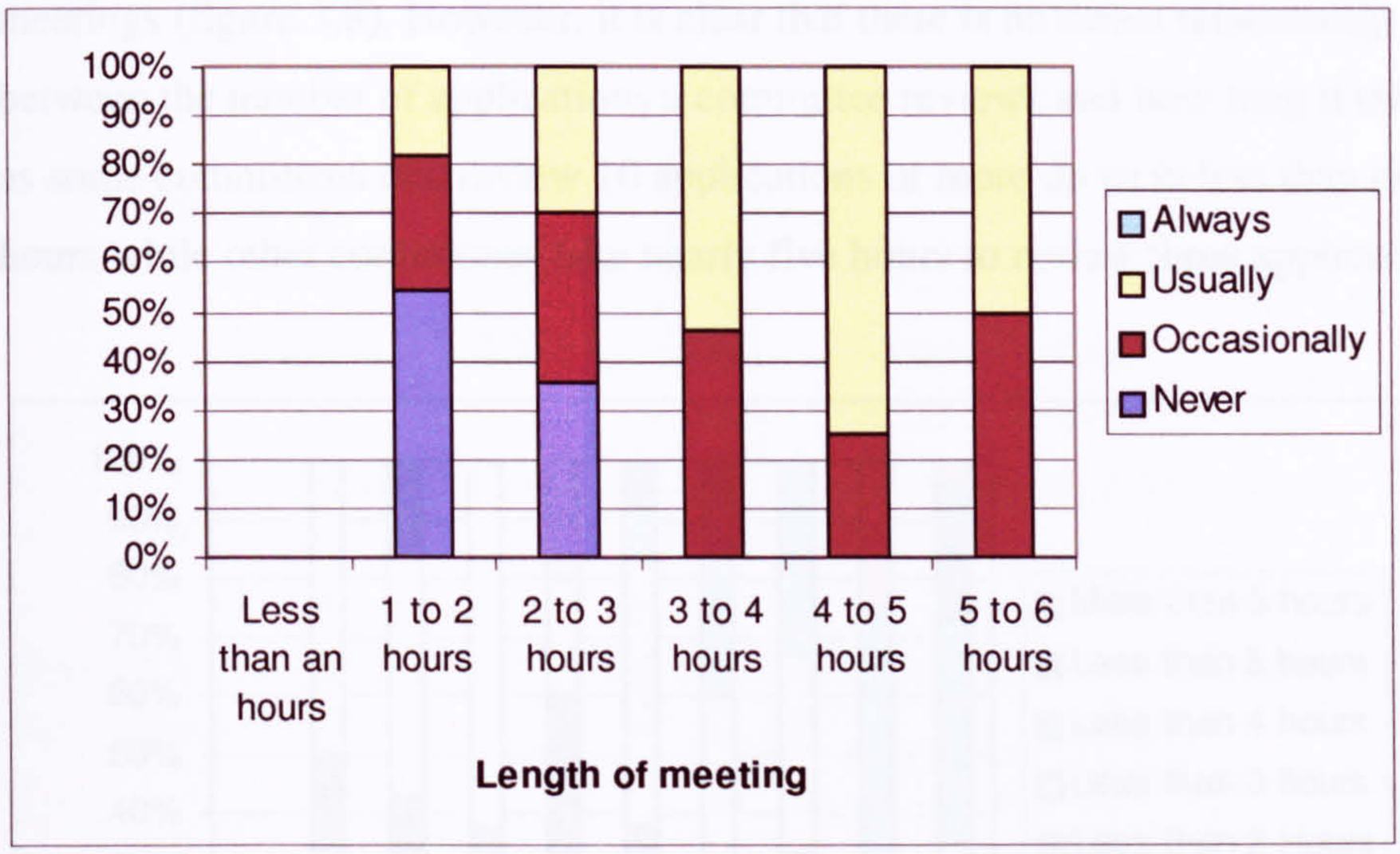

Figure 3.6 A chart showing length of meetings by researcher attendance (n=90)

LRECs reported a huge variety in the number of applications reviewed in each meeting (figure 3.7). 30% of committees review 10 or more applications each meeting, while 25% review less than five.

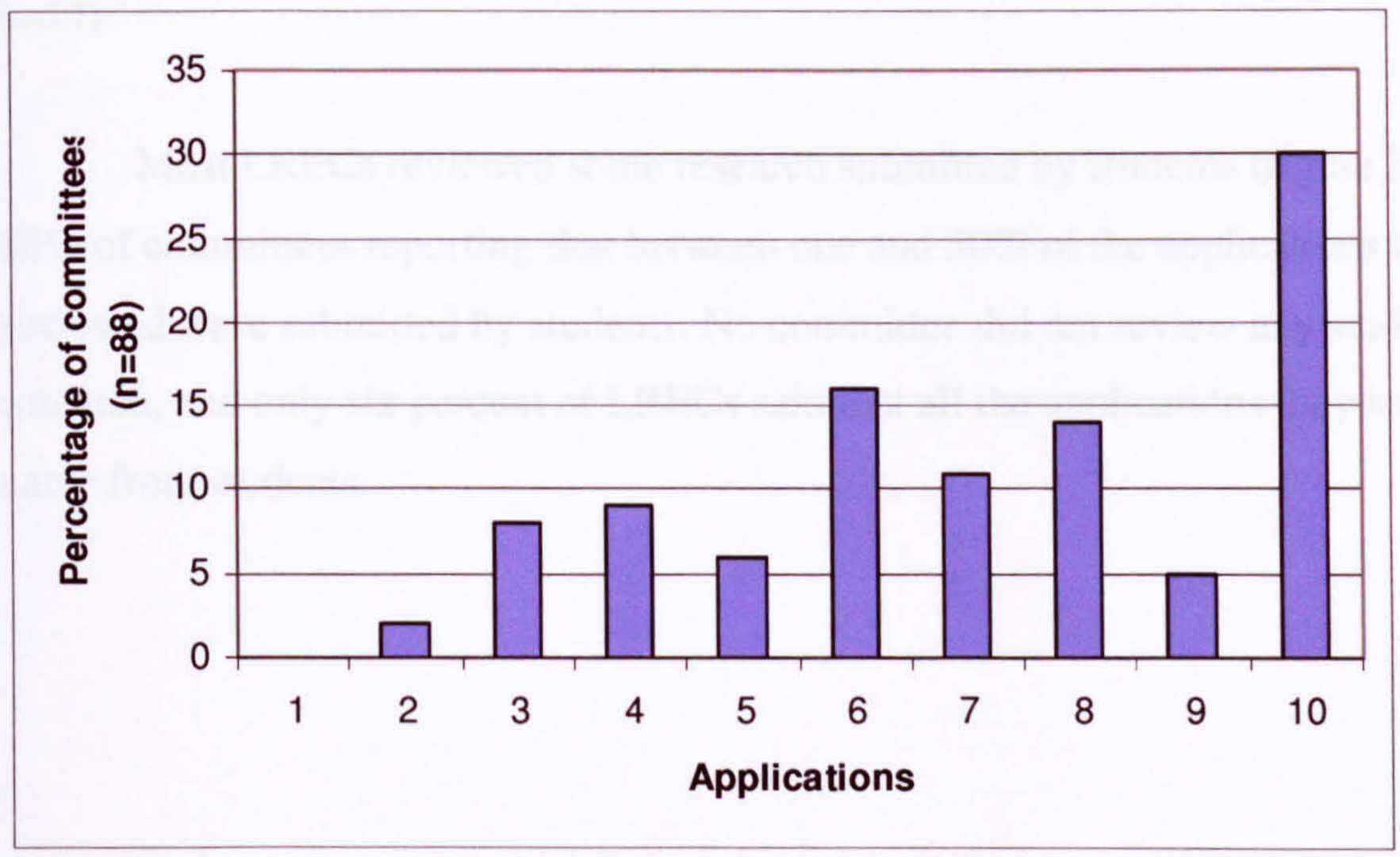

Figure 3.7 A chart showing the number of applications reviewed in LREC meetings (last 3 months)

There is some correlation between the length of time meetings take and the number of applications reviewed, with fewer reviews generally indicating shorter meetings (figure 3.8). However, it is clear that there is no direct relationship between the number of applications a committee reviews and how long it takes, as some committees that review 10 applications or more do so in less than two hours while other committees take nearly five hours to review three applications.

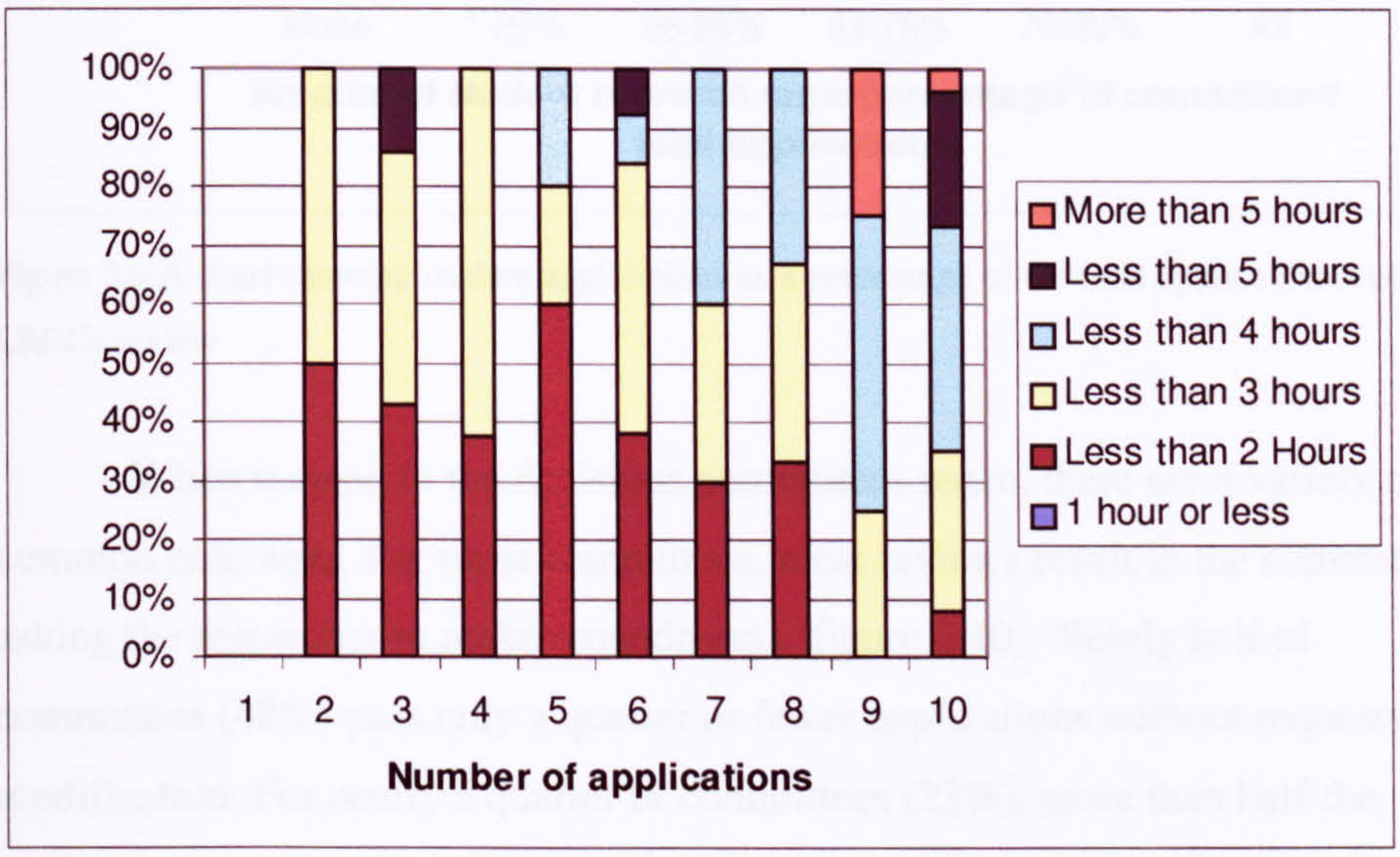

Figure 3.8 A chart showing the relationship between length of committee meetings and number of applications reviewed

(n=87)

Most LRECs reviewed some research submitted by students (figure 3.9). 88% of committees reporting that between one and 50% of the applications they reviewed were submitted by students. No committee did not review any student research, and only six percent of LRECs said that all the applications they had came from students.

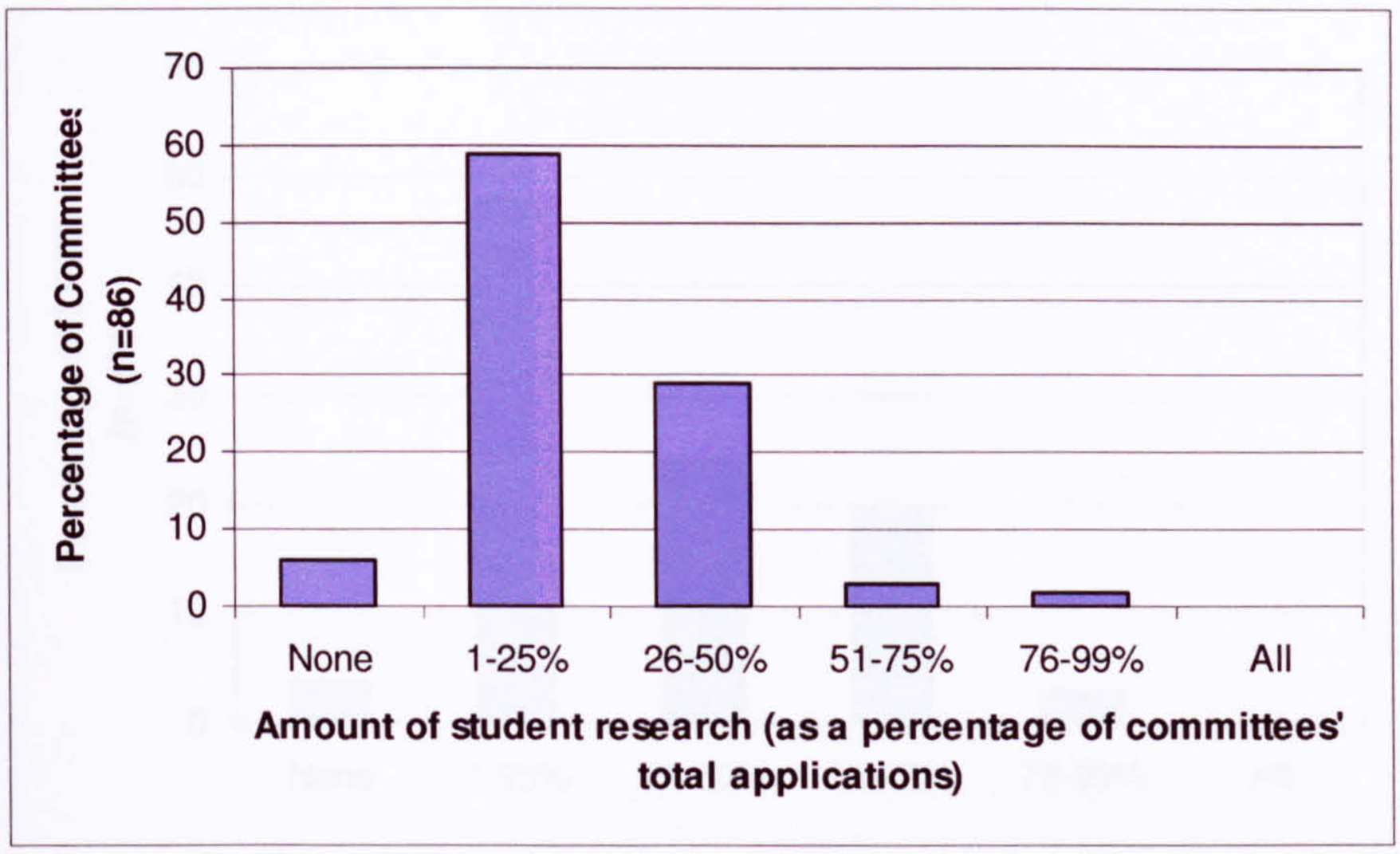

Figure 3.9 A chart showing student applications as a percentage of the total applications each LRECs review

When it came to the decisions committees reach, there are a variety of common outcomes. For most committees, most reviews result in the committee asking the researcher to make amendments (figure 3.10). Nearly half of committees (48%) pass only a quarter or fewer applications without requests for modification. For nearly a quarter of committees (23%), more than half the applications they receive are passed without any request for clarifications or amendments. No LREC reported always passing applications without amendments.

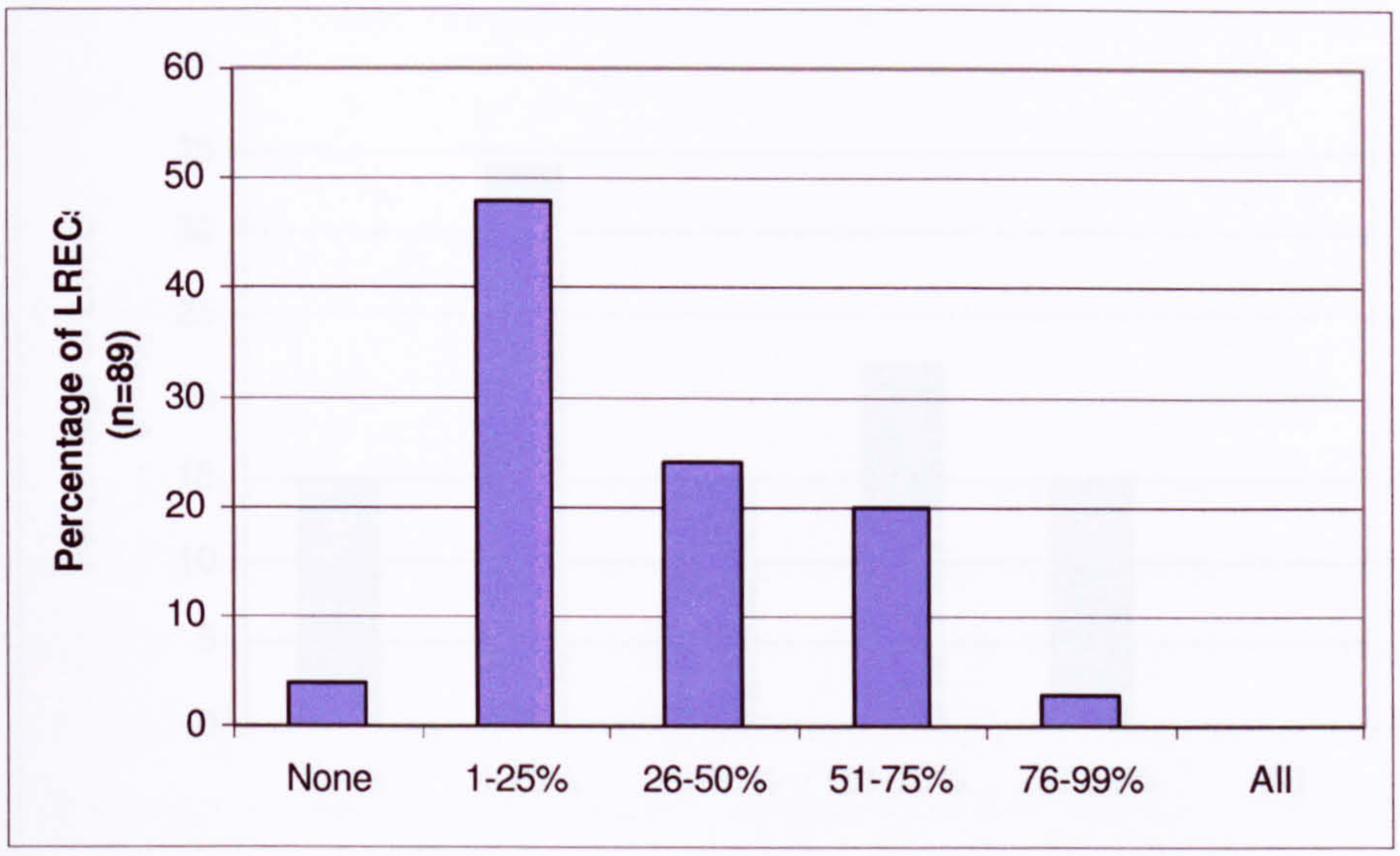

Figure 3.10 A chart showing percentage of applications to each committee approved without modification

If an application is not passed without modification, but the required amendments are minor, committees might approve the application subject to the chair of the committee seeing the requested amendments. This is known as chairs' action. 15% of committees reported no applications are approved in this way, but 37% approve more than half of the applications they see in this way (figure 3.11). If the amendments needed are more serious, LRECs write to researchers asking them to make changes and then resubmit the application. In such a way, an application is given a second full review. Most committees reported that they reviewed only a few (or no) applications for a second time (figure 3.12). Only 3% of committees reported reviewing 50% or more of the applications they received for a second time. 8% said they never conducted a second full review and over three quarters (76%) said that between one and 25 % of applications received a second full review.

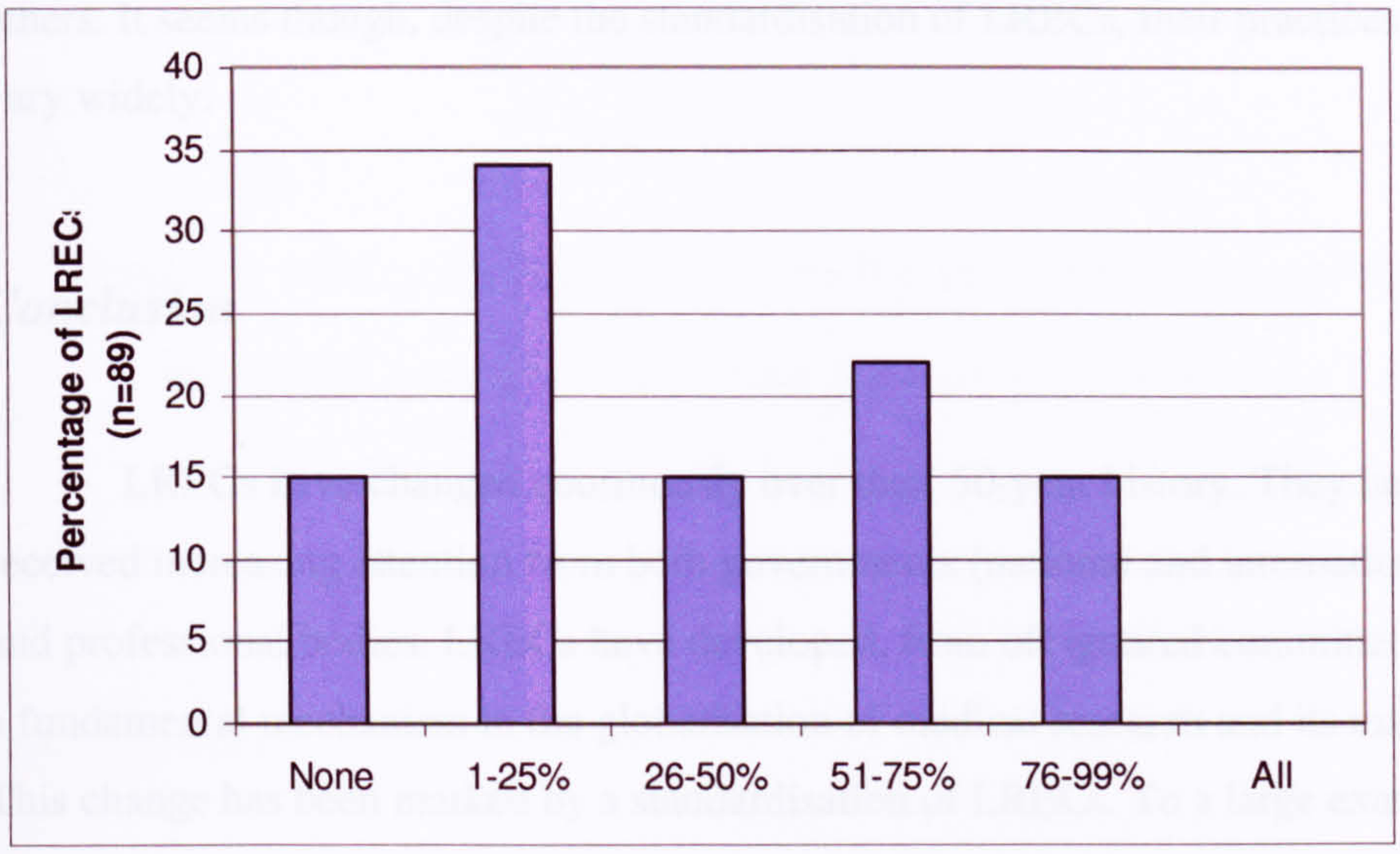

Table 3.11 A chart showing the percentage of applications to each committee approved subject to chairs action

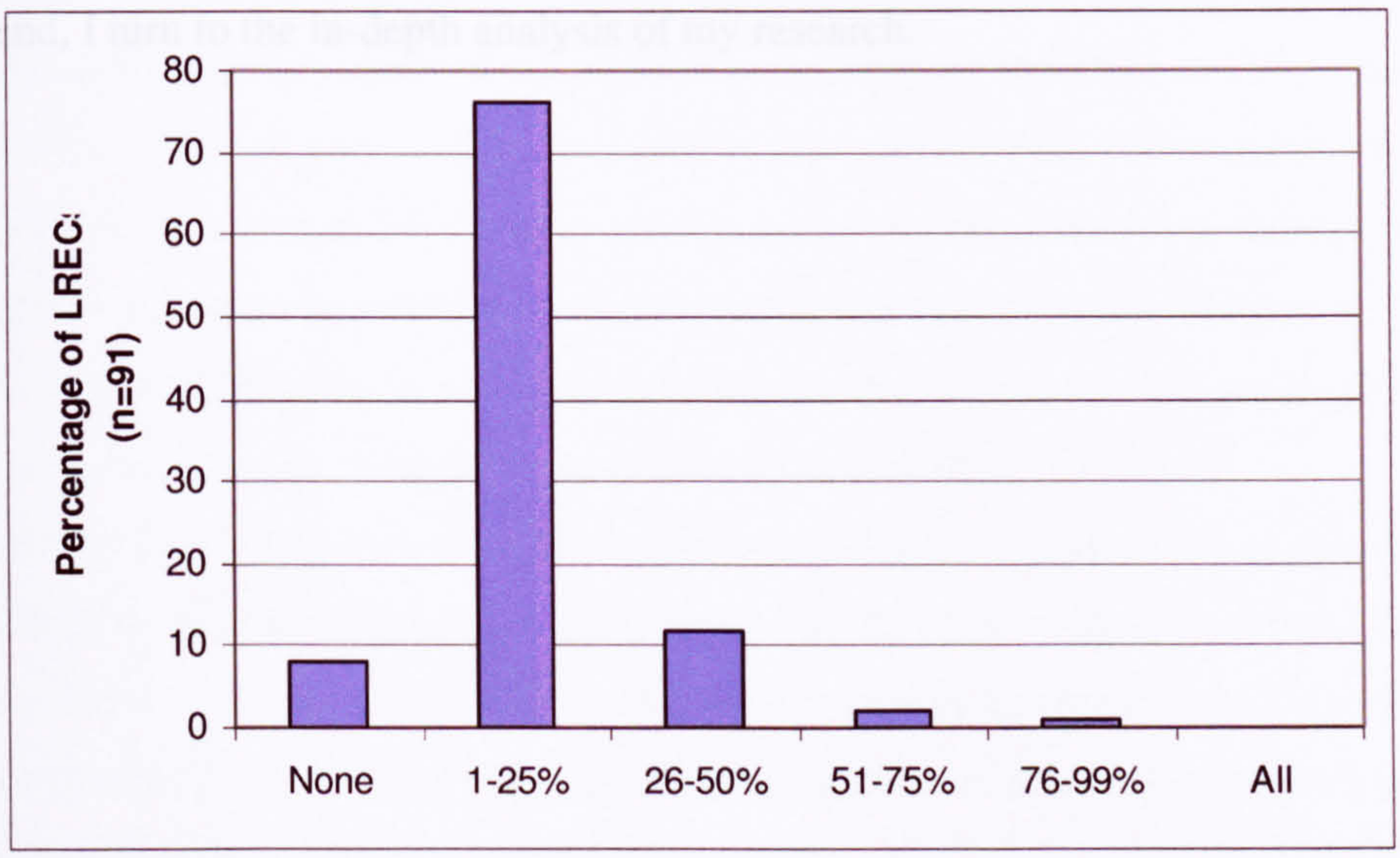

Table 3.12 A chart showing the percentage of applications to each committee to receive a second full committee review

The number of applications that different committees review each meeting varies hugely, as does the length of meetings. Some applications are reviewed in a matter of minutes (where 10 applications are reviewed in two hours) and others take over an hour (3 applications reviewed in just less than 5 hours). Some applications will, of course, be more ethically contentious than

others. It seems though, despite the standardisation of LRECs, their practices still vary widely.

Conclusion

LRECs have changed enormously over their 50-year history. They have received increasing attention from both governments (national and international) and professional bodies. LRECs have developed, from oft ignored committees, to a fundamental mechanism in the globalisation of medical research and its market. This change has been marked by a standardisation of LRECs. To a large extent the standardisation measures have been successful measured in terms of the number of members LRECs have or how often committees meet. However, such figures tell us very little about what actually goes on in LREC meetings. To that end, I turn to the in-depth analysis of my research.

Chapter 4

Putting ethics in its place: drafty committee rooms, nervous researchers, and lots of paper work

Introduction

The notion that ethics needs putting in its place implies it is somehow currently out of place. It implies, perhaps, that ethics has got 'too big for its boots' and needs to be re-confined to the places it belongs. Indeed, flicking through the letters pages of the medical press, such as *The BMJ* and *The Lancet*, we might be left with such an impression. Is it not, after all, ethics committees who delay research, ask for amendments based on their misunderstandings of research, and make some research projects altogether untenable? This new role of ethics committees as gatekeepers in the research process might easily provoke a response akin to 'who do these people think they are?' The recent standardisation of ethical review might even be construed as an effort to keep ethics in its place. For while ethical review has become obligatory, what it entails has been codified (and thus limitable) in Governance arrangements (Department of Health, 2001a)[5]. Such is one possible assessment of the recent standardisation of ethics committees.

The project of 'putting ethics in its place' that I attend to here is very different. In this and the following chapters I give an account of bioethics which takes place[6] to be central, in this instance the places of Local Research Ethics Committees (LRECs). As I described in chapter two, philosophical and professional Bioethics have evolved to answer the ethical questions created by

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[5] Hereafter referred to simply as the Governance.

[6] I use the term place to describe the time-spaces of LREC meetings. I do not take these to be discrete or abstract, but relational and socially constructed spaces.

advances and applications of medical science and technology. Both these questions and the answers to them are formulated as universal ones, separable from the times and places in which they occur and will be settled. In my counter-analysis of the 'ethical' issues arising from bio-science, place is taken as central. Rather than assuming these sorts of problems and solutions to involve the application of a set of principles, I take bioethics to be something that has to be understood in terms of the people, places, and things that come together to make something happen, a bioethical decision. I call this emplaced ethics.

In its rendering in conventional Bioethics, then, ethics is out of place because it is studied as if it has no place. This thesis puts ethics back in place (and place back in ethics) by treating the site of ethical deliberation as integral to any analysis.

Sitting in LREC meetings, I could not help but be aware of how utterly different they were from academic Bioethics. My experience of Bioethics is largely typified by reading and writing. In written texts arguments are presented within a logical structure and have a position of which the author is trying to convince us. We are told of the facts the author judges relevant to the case, not those that are not. Using what we might called the philosophical method, we engage with these texts asking a number of questions: what conclusion is the author trying to reach? Why is that conclusion interesting? What is the argument? Is it logically valid? Do we accept the premises of the argument? What follows from the conclusion? (The philosophy panel of the University of London, 2000). If there is a section of an argument we are not sure about we can mull it over or read it again. None of this is so in an encounter with an ethics committee.

That academic texts and committee meetings are different is hardly a shocking pronouncement. However, it is in this gap between the two that the fallacy of 'applied' rests. Saying that universal principals are taken and applied in practice, in this case by LRECs, obscures far more than it clarifies. LREC discussion does not 'abstract away the particulars' to reveal the universal, rather it reasons through the particulars. As I describe below, a whole host of people

and things come together in particular places to have bioethical discussions. Putting ethics in its place requires that we produce micro-geographical analysis that shows the ways in which different spaces matter in the production, circulation, and consumption of ethical knowledge. We need to move beyond 'applied ethics' to 'emplaced ethics'.

To this end, this chapter describes the spaces of LRECs. It begins with a general introduction to the spaces of LRECs. It then describes three important factors in the production of spaces: the paperwork, the researchers, the committee members, in each description drawing out the uncodified ways in which each contributes to LRECs' bioethics. The chapter ends by outlining three fundamental differences between Academics' 'applied' Bioethics and LRECs' emplaced Bioethics.

Local Research Ethics Committee meetings

Attending an LREC meeting disrupts the notion of bioethical argument as 'a highly rational, formal, largely deductive mode of argumentation' (Bosk quoted in Hedgecoe, 2004; 124). Unlike academic Bioethics, it is not clear where an argument begins or ends. For example, discussions between the chair and the administrator at the beginning of the meeting can curtail the time a particular review is allowed, and the way in which the administrator interprets a committee's discussion in his/her letter to a researcher or minutes impacts on the decision that has been made. Whilst open in this way, committees' bioethical discussions are also bounded by the time constraints of the meeting, by the 'rules' of committee meetings, and other pre-existing social relationships. There are many voices, not one, and arguments are made not just with words but also with other noises (such as sighs), with movements (such as nods), and with silence.

The rest of this thesis aims to describe LRECs and their emplaced bioethics. I begin by describing meetings and highlighting some of their relevant features.

Figure 4.1 A LREC meeting in progress

Although their Governance states LRECs are 'independent' committees (Department of Health, 2001a: 2.5), the physical surrounds mark them out as part of the structure of the Health Authority[7] and the National Health Service (NHS). All of the committees I attended took place on NHS property. In all but a couple of cases the meeting was held in a NHS administration building. Committees sit around a table during their meeting. For some committees this is a rather splendid huge oak table surrounded by oil paintings in a grand boardroom. More often than not, though, it is Formica tables pushed together in a drafty room at the back of a hospital somewhere. The surroundings of these meetings set them apart from the rest of the day. The meetings happen at designated times and in designated places. For even most professional members (doctors, nurses, and so on), who serve the committees by virtue of being employed by the NHS, their working life is spent in hospital wards, offices, laboratories, and operating theatres rather than committee rooms. For lay members of the committees, such surroundings also mark out the meeting as a separate part of their day.

Generally, the committee administrator, a health authority employee, arrives well before anyone else. At all but one of the committee meetings I attended the administrators were women. I did not conduct formal interviews with administrators. At the beginning of this research, this omission reflected my

[7] From this point onwards Health Authorities will be referred to as health authorities.

own prejudices about what constitutes a committee. As my research progressed, though, I realised the importance of the administrators, not only in the smooth operation of the committees but in the decisions they reached. Administrators had huge knowledge of the Governance, the working practices of other committees, and the decisions their own committees had made in the past. They were in the front line of people the Department of Health was training and were beginning to be well networked through attendance at training. Despite their importance I decided not to try and conduct formal interviews with committee administrators. In part this hung on the difficulty I believed there would be in recruiting and interviewing administrators whose committee work is paid and treated as lower in the professional hierarchy of medicine. I decided the difference would be difficult for me as a researcher and might prove embarrassing or cause anxiety for the administrators. Despite the absence of formal interviews, this research takes the role of administrators very seriously.

Figure 4.2 Administrators taking notes during a meeting

In this meeting one administrator was work shadowing another. Administrators take notes throughout committee meetings while members are unlikely to do much writing during the meeting.

Committee administrators set up the room for the meeting. They bring a number of things with them to the committee. In about half the meetings I attended each committee member had a name plaque made of card, which was put on the desk in front of them. They also brought all the files and paper work they needed for the meeting, along with pens and paper with which to make notes for the minutes of the meeting. As I have said, committee administrators contribute to the bioethical discussions of the meetings. They necessarily interpret committee discussions and decisions in the letters they write to researchers summarising the committee's review and in the minutes of the meeting they write. Administrators might also be called upon during the meeting to recall the committee's past decisions or points of the regulations. Indeed, given, as I argue below, the importance of the paperwork that circulates making ethical review possible, the administrators' role is a key one. Administrators, though, serve the committee rather than being part of it. As well as the important work of preparing paperwork they also do the fetching and carrying and setting up the room.

Often the administrator's first job on entering the room is to set up the food and drinks for the meeting. A lot of committees meet at lunchtime (my survey found thirty one percent) or in the evenings (thirty percent). The committees I attended at these times had a lunch of sandwiches, fruit, and biscuits. Clingfilm is taken off plates of sandwiches, napkins and plates laid out. When there isn't food provided there are tea, coffee, and biscuits to be laid out. While economists are want to say there is no such thing as a free lunch, the food provides at least one tangible compensation for the time unpaid committee members otherwise freely give. The food and drinks provided by the health authority marks out the meetings as apart from other activities in committee members' days. It marks out the committees as one, for it is they and not researchers who might attend, who share food.

Figure 4.3 Food and drink, a space apart from the working day

Usually the chair of the meeting arrives shortly after the administrator. The chairs and vice chairs of the committees, the people likely to be chairing each meeting, are predominantly white men. The survey data I produced shows that nearly three quarters of chairs are men (74%) and a slightly smaller percentage of vice-chairs (69%). Most chairs (87%) and vice-chairs (94%) are ethnically white. Nearly half of chairs are medical consultants (48%) and nearly a further third are lay members (27%). Three of the committee meetings I observed had lay chairs. One was a retired business man doing voluntary work he thought used his skills well; another was a hospital's chaplain chairing the committee as an extension of his pastoral care; and yet another a business consultant increasing his knowledge of the NHS. As I describe below, the person chairing the meeting is very important in the decisions that get made. It is sad but not unexpected that these positions of power are mostly held by white men.

The chair and the administrator then have a chat about the running order of the meeting, about any paperwork that they were waiting on that has turned up, that sort of thing. While this is going on members begin to arrive. Getting themselves something to eat or a cup of coffee, they sit down or stand round

chatting. The topics of conversations range from work related issues to general chit chat about what is going on in the news to holidays and so on. In this respect LREC meetings are much like a thousand other meetings going on around the country at the same time.

As with many other meetings, many LREC meetings begin with the chair calling the meeting to order with a phrase something like the one I heard over and over again:

> We've got a lot to get through so shall we get started...

At this point the room tends to become quiet, but for the noise of members shuffling papers or pulling chairs in. All eyes are towards the chair. The role of chair is to direct the meeting, deciding when discussion has become superfluous, when one member is dominating the floor, and so on. In this role the chair is not one voice among many in the meeting but has considerable power over the direction discussion takes.

LREC meetings are essentially 'closed' meetings in that non-committee members do not have an automatic right to attend. There have been some calls in the medical press for meetings to be open to the public (Ashcroft and Pfeffer, 2001). Most members I spoke to, though, felt this would compromise their review. People are able to observe meetings with the permission of the chair of the committee. If there are any new members or observers they are introduced at the beginning of the meeting. I only witnessed a couple of meetings where an observer was present. In one, the chair of a neighbouring LREC attended as part of a reciprocal agreement intended, as a member of the committee explained to me, to increase trust between the committees and see if either could learn from the practices of the other committee. The visiting chair invited any of the committee to attend his committee's meetings although none thought they would have time to do so. In another meeting, a newly appointed Central Office of Research Ethics Committee (COREC) local manager attended the meeting. The committee seemed unsure whether they were being checked up on or not and

were much more wary and tentative in their discussions than other committees I had seen. On both occasions the observer sat at the table with the committee.

After the meeting has begun there is some business to get through before the review of medical research can begin. The chair of the meeting circulates a revised meeting agenda, if there is one, and checks the meeting quorate, i.e. are at least seven members present (including at least one lay member and one expert member) (6.11). I was never quite sure whether this sometimes self conscious announcement was for my benefit or not. In the end though it seemed more a response to the tightening up of the regulation of the committees, a conscious effort both to obey and to be seen to obey the new regulations. In a couple of the meetings I attended the meeting was not quorate. In one, the chair waited to start until another member arrived making the meeting quorate. This involved researchers who were to attend the meeting being kept waiting for almost an hour. In the other case the chair began the discussion but said no decisions could be made until another member of the committee arrived. Meetings begin with a review of the previous meeting's minutes and as the meeting progresses latecomers arrive, excusing their lateness apologetically. It is absolutely normal for a few members to be late. This might be a consequence of the working patterns of health professionals or it might be a reflection of the fact that committee work is unpaid.

LREC committee meetings then are much like a whole host of other meetings. They are able to work because everyone in attendance understands the rules of these sorts of meetings. This is something chairs of committees, at least, are aware of when recruiting lay members for the committee (an issue to which I return in chapter eight where I discuss the recruitment and role of lay members on the committees). Equally, this everyday quality of the meetings disrupts the academic rendering of Bioethics. The setting and structure produce a very different way of 'settling on' assessments of the ethical questions posed by medical research. A host of actors have made decisions about the ethical nature of each piece of research before it gets to an LREC, about what information is relevant and how to present it. The Governance of LREC structures both the constitution of LRECs and the discussions they have. Meetings in their very

essence consist of many voices and introduce pre-existing social relationships. Furthermore, meetings introduce time constraints and materials that mediate relationships with distant spaces. It is this material that medicates relationships with distant others, the paperwork, that I turn to in the next section.

LRECs discuss each of the applications in turn, as set out in the meeting agenda. If discussions of the first applications take too long it means that later applications have to be given less time. The chair directs the discussion of each application. The chair will end with a summary of the findings of the committee, sometimes checking with the administrator that the points had been written down. It was clear that interruptions from other members of the committee were not welcome during the summary.

After having reviewed all of the applications that have been submitted to them for review the committee turns to other tasks. Primary among these is the locality review of MREC approved studies. I discuss this in chapter six so I will only say here that this is a very uncomfortable process for LRECs. Quite often the paperwork for these applications goes to a subcommittee of two to four members. The chair then goes through other paperwork, such as any adverse outcome reports or end of study declarations. The chair usually just advises the committee that this final report or that adverse outcome form has been received and that they can get a copy of it from the administrator should they wish. The chair then tells the committee of any up coming training and tells the members to talk to the administrator if they wish to attend. The meeting ends with the chair advising the members of the date of the next meeting. Throughout all these discussions the administrator is taking notes in order to write to the researchers and inform them of the decisions made by the committee and write up the minutes of the meeting. At the end of the meeting, the chair and the administrator often have a quick chat or a more formal meeting where they go over the decisions that have been made.

After all the business of the meeting is done members leave and the administrator is left to tidy up the meeting room ready for its next occupants.

The Paperwork

While LRECs resemble many other meetings their task in hand is particular to them: to review the applications submitted to them. Whatever the differences between LRECs themselves (efficiency of the administrator, style of the chair, number of applications) what all meetings have in common is that the twenty or so people all sit with a pile of papers in front of them. They all have at least one aim in common: to review the applications in front of them in the time allotted and then go home or back to work. This paperwork is central to their review. It holds the information they are to assess, it serves as proxy (a well filled in application form can signal a seriousness about ethics), it is part of the 'particulars' through which LRECs reason.

The paperwork is an active component in meetings. It makes certain decisions possible and others not. It must therefore be an important part of any analysis of emplaced ethics of LRECs. Without knowing the material through which the review is performed we could not know the review (Mol, 2002). The decisions that committees make, the ones that are minuted, are hybrid achievements spun between people and things. As Latour says,

> '...and we insist and insist again that there is a social history of things and a "thingy" history of humans.....' (1999: 18)

In chapter six I consider in more depth the 'thingy'-ness of the particular human subjectivity LRECs' participant information sheets and consent forms are implicated in constructing. For the time being though I turn to the role the paperwork generally serves in LREC bioethics.

I describe first the standardisation of the paperwork and committee members' responses to it. I then turn to LRECs' reading of the paperwork, first, in private by themselves and, then, collectively as a committee. I conclude with an observation of how it is this paperwork that persists after the bioethical discussion is over.

Standard paperwork

In the past the huge variety of application forms LRECs used to have was a constant cause for researchers' complaints (Lewis, 1982, Black et al., 1995). The ethical review application form and guidance for participant information sheet have now been standardised (Department of Health, 2003, Central Office for Research Ethics Committees, 2001). The Government set up a working party to write the participant information sheet guidance and another to write the standard application form. These standardisation processes are another tale that is yet to be told. Its success has been crucial to the project of a workable standardised research ethics committee system.

The standardisation of consent documentation was a project that rested partly on technology. The standardised application form is very long because it covers possible ethical problems for disparate types of research. Software was designed to enable a 'smart' application form. As applicants filled in the form unwanted sections would be removed. For example, if a researcher entered a 'no' in the question about whether the research involved administering new drugs then all other questions about new drugs, whether they are licensed for example, would be removed in the smart form. There were rather a lot of technical difficulties with the software at the time of my fieldwork. It meant the government had to delay the adoption of the standard application form by LRECs. Many LREC members I spoke to saw these set backs as symptomatic of the problem of standardising ethical review. For some it undermined their confidence in the whole project of standardisation. They saw it as evidence of the incompetence of the Central Office of Research Ethics Committees (COREC). For other members, though, it just highlighted further the need for a standard form. A lay member with a background in law described this situation to me:

> [At the moment] every form has been developed by each committee. That is one of the huge problems. COREC has written [a standard form] and it was supposed to come in April this year but they have experienced some problems with the standard form. The Multi-centre Research Ethics

> Committees already use it and the LRECs can use it but most still have their own, most still use their own. We do. It is largely like the standard form and I don't think that it will change that much. When COREC announces that it becomes standard everyone will have to get that form off the COREC website and use it. That will take care of a lot of the problems. C36

At the time of this interview, October 2003, LRECs had just begun to share the review of application made within each health authority. This meant that LRECs were reviewing applications made on the forms designed by other committees. The member quoted above sat on a committee that had to conduct just such a review at a meeting I observed. The other committee's application form did not include a question about whether the data protection act would be complied with. The lay member I spoke to felt, without such a question, the other committee was not properly undertaking its duty. Standard application forms then are a mechanism for engendering trust between committees as well as between RECs and other stakeholders.

Although a number of application forms were in use at the time of this fieldwork, the standard template and guidelines for participant information sheets and consent forms were in use. Researchers had to go to the 'applicant section' of the COREC website and download the template participant information sheets and consent forms. They then had to write their own participant information sheet and consent form and submit 18 copies of these, their application form, and their research protocol to the committee's administrator. It is these bits of paper that LRECs consider in their ethical review of medical research.

Whilst ethical theorists might discuss the primacy of this principle or that, committee members address the paperwork in front of them on their desks. Some committees also sometimes see the researcher in person. Always though a completed application form, copies of the research protocols, copies of participant information sheets and consent forms represent the application the committee will review.

Reading the paperwork

Members start the meeting with twenty centimetres or so of papers in front of them piled in the order to be discussed, as set out in the agenda. Committee members then move papers to form another pile as applications are discussed thus physically marking out the movement through the meeting. However, this will not be the first time they have performed these actions. The scribbles and highlighter marks tell of an earlier movement through this pile of papers. This earlier reading was performed, not in public, at a designated time and place but in the privacy of members' offices or homes. Some professional members describe reading the protocols at work, one or two at a time if they have a 'quiet hour'. Others, such as a doctor I interviewed in her office, told me they were sent to work but often she ended up taking them home and reading them in her own time:

> [When they arrive] I put it over there, ooh I have got one over there [now]. I try and read them, but usually take it home over the weekend, and read it then, before the committee. C15

There is a sense in the answers that professional members gave that the committee work is slightly apart from their day-to-day professional life, something that they do in addition to rather than as part of their normal workload. For lay members this is certainly true. The paperwork is sent to their homes rather than their offices. As a retired nurse, a lay member of one committee explained to me when I asked what she did when the paperwork arrived at her house:

> First thing I do is look to see if I'm lead scrutiner and then you need to look at it [the application] quickly because if you think that you could do with the researcher coming in you need to let them know quickly....Go through minutes and then you go through each protocol in turn and take your highlighter and highlight the bits and pieces that say things. And then make a note of things that you need to ask and sometimes that is answered as you go through the papers and sometimes it isn't. Then you make a list of all the points that you want to make at the meeting. C5

This first private reading of the paperwork is an important responsibility of being a committee member. It is time consuming, many committee members estimated it is two days a month work. The conditions of these readings, skimmed through on the bus or given time at a desk with a medical dictionary, will make a difference to what happens at a committee meeting.

The paperwork is an active part of the meeting. Members are constantly skimming through, flicking backwards and forwards, trying to find some notes they made in the margins. In the words of one lay member I spoke to:

> [The meeting] in itself is the culmination of a months work. Everyone has received the paper work. I sit down, scan through them as they arrive. Just, sit down with a cup of coffee and let's see if something jumps out. Then when I have time I really go through them. Because I have done it for quite a while now I know what to look for. As we are talking and listening I keep looking through and it refreshes my memory. C44

The paperwork that regulates meetings is central to members' description of the meetings and their decision making. A professional member, an active researcher, who might be thought to be more 'at home' with research protocols and the like, said this:

> I try and read all the forms the night before to let it sink in. I cannot read these things in a rush. The forms are very awkward, and the way we present, leads to a lot of to-ing and fro-ing. But it is very worthwhile as putting the effort in gives a lot back. C16

What becomes clear from listening to members describe preparing for meetings is that the application forms and accompanying paper work are not 'transparent' or 'open'. Even committee members with a background in medicine and experience serving on a LREC must take time to make sense of the application form and other documents.

Reviewing the paperwork

Most committees have a system whereby one or two members are assigned as lead reviewers on each application. If there are two reviewers it is usually one professional and one lay member. As the retired nurse (C5) quoted above says, the lead reviewer is assumed to have to undertake a more thorough pre-meeting reading of the application. They then 'lead' the movement through the paperwork in the meeting. Lead reviewers are either picked at random or, on a few committees, chosen because they have some expertise in the area of the research. Some committees, such as the one the lay member quoted above sits on, have a form for the lead to fill in:

> If you are lead scrutiner then we have a form which we fill in. You don't have to but it helps and it helps [the administrator] to have a written record of what the lead thought. We tick the boxes if they are ok and make comments where necessary. The scrutiner leads the discussion but we have all read it in detail but you miss things because you don't know about them. This is why you have a committee. C5

The committee members who lead review (or scrutinize) on each application set the tone of the debate and have first shot at interpretation of the paperwork. As the retired nurse implies this interpretation is open to re-interpretation by other members of the committee but the lead sets the stage.

This stage of each review, which I call the introduction, begins when the chair invites the lead reviewers to make comments on the application. On committees where two members lead review applications one will give the introduction and the other might make a few comments at the end. If a lead reviewer is unable to attend a meeting it is normal for them to send written comments to the meeting. These are read to the committee by the chair. There are exceptions to the lead reviewer model, although not many. In one committee I attended the chair introduced and summarised each application, in another no one did and the floor was opened to anyone who wanted to comment from the outset.

The introduction is, as I say, an opening interpretation of the paperwork. In this introduction phase of each review, the lead reviewers begin by identifying the application with its name and maybe its application number and the name of the researcher. They often then give a summary of what the research would entail. These generally include details of the research question/hypothesis (with a description of standard treatment for the medical condition if appropriate), the number of participants to be enrolled and what would happen to them. The introduction invariably includes an assessment of the consent procedure including a description of how potential participants would be identified and an assessment of the participant information sheets and consent form the researcher has submitted. In this summary, committee members will usually say if it is student research or work by an experienced researcher. Where the committee has experience of a researcher or research team, this is often mentioned at this point. Lead reviewers then give a summary of what problems they see with the research. Typical final comments might be 'this is a poor application but only what we have come to expect' or 'this is good research that should be being done by a researcher who has a long list of published research in this area'.

During this process of introduction, which tends to last a few minutes, lead reviewers spend a lot of time looking at the application form in front of them, glancing up at the committee. A few lead reviewers write themselves a summary of their views but most scribble the main points on the front page and have notes elsewhere in the margin or scribbled across the text. The rest of the committee are either furiously skimming through the forms to try and prompt themselves into remembering their thoughts, or else watching the lead reviewer and glancing at their own copy of the application form. As described above, some committees have developed summary sheets – with a series of questions the lead review needs to address: i.e. is the methodology clear? Has the researcher given participants enough time to consent? etc. In one committee I visited, this form, completed by each lead reviewer and emailed to the administrator before the meeting, was displayed on an overhead projector. In this meeting, it was this projection rather than the lead reviewers themselves, that held the committee's attention during the introduction.

After the 'introduction' of an application the chair will open the floor for further discussion. If the introduction was given by a lead reviewer, and not the chair, the chair might provide some guidance on the lead's interpretation of the application form. After the introduction there is a discussion of the application. This discussion can be divided into two stages. In the first stage the committee aims to produce an agreed interpretation of the application and its potential problems. In the second stage it seeks to 'settle' the bioethical problems.

The first stage of the discussion of an application is used by committees to develop a shared understanding both of what the research involves and what ethical issues are at stake. The difficulty, even for experienced committee members, of reading an application and gaining a picture of what the research will involve should not be underestimated. Everyone I spoke to stressed the importance of the committee system in accomplishing this task. As the chair of one committee said:

> ...the fact that the committee actually meets to discuss it is a great strength because often we start to bounce ideas off each other and we realize that there is an elephant in the room and no one has realized. C3

The initial part of this discussion will be, in effect, an assessment of the introduction. The members have either to agree or disagree with the assessment made by the lead reviewers. It is often quite a surprising stage in the review because members can start off with divergent understandings of the research and misunderstandings of other members' understandings. Through discussion views change quickly and then may change back. One member who has expertise may be called on to explain the application to the rest of the committee. Alternatively, two or more committee members may engage in trying to clarify what the research actually entails (one set of blood tests or two? Are they intending on storing the blood samples or not?). These sorts of discussions are typified by flicking backwards and forwards between different sections of the application

form, trying to gain a coherent reading of the research or rather of the application paperwork.

The second stage of the discussion of each application is aimed at settling the bioethical problems arising from the research. This stage is, in a sense, the subject of the rest of the thesis, an exploration of the spaces of LRECs and their production of certain settlements of bioethical discussions. What it is worth saying at this point is that LRECs do manage to settle the bioethical problems arising from the research they review. In the meetings I observed, committees asked for amendments to be made, for sections to be re-written and re-submitted. They occasionally refused to review applications because they were outside their remit. I rarely, though, if ever, saw a committee reject an application. (It may be, of course, that their requirements made research practically impossible.)

As well as providing information for the committee and a prima facie reason to reject an application (or ask for amendments), the paperwork 'acts' in the review in other ways. For example, committees often make assessments about whether the application form has been filled in well. When committees do not think a form has been filled in well they can interpret this as signifying a lack a concern with ethics more generally. But even where a form has been filled in well it can still take committees a fair amount of time and discussion to develop an agreed understanding of the research and the ethical issues it raises. When a committee is not able to come to an understanding, clarification will be sought from the researcher and the approval delayed until a later committee meeting or, if the matter is thought to be straight forward, to a later chair's action.

The persistence of the paperwork

LREC review is removed in time and space from the medical research it assesses. It is no wonder then that the paperwork that mediates the relationship between committees, researchers, and the Government is key to understanding LRECs and their review of medical research. Inevitably the information required on the application form becomes, within the LREC setting, more ethically pertinent. In chapter six I return to the way these issues have shaped ethical

review and in particular informed consent. The paperwork does not merely provide a neutral container for information. It shapes the review. The paperwork structures meetings. It is fundamental to LREC members' understandings of the task in hand. The paperwork must be actively 'read' by committee members. This can include value judgements read from the forms about how seriously a researcher has taken the application. A member's ability to handle the forms in a meeting can lead to arguments being won or lost. If members cannot find the relevant section of the paperwork then the debate may move on while they search. The opportunity to make a particular amendment is lost. These material aspects of LRECs' bioethical discussion are wholly absent from academic renderings of debate.

After the meeting has finished and the decisions have been made, members tend to take these papers with them and file them in the office or at home. At a couple of meetings I attended the administrator collected the papers in order to dispose of them as confidential waste. Where a committee asks for changes to be made to the participant information sheet or consent sheet, and they usually do, the researcher resubmits the amended forms. They are checked by the chairs of committees against the list of requested amendments and then accepted under chair's action. Copies are sent to the whole committee for information. The administrator then files the final set of papers in order that they can be called on in the event of any problem with the research.

Figure 4.4 The approved applications in boxes waiting to be filed

The approved participant information sheets and consent forms are supposed to be used by the researchers when they are recruiting participants. But the committee can only make assumptions about what happens once the LREC has given its approval to research. Their review is anticipatory. It says on the consent sheets they approve that three copies will be signed and given to the researcher, the patient, and one shall be kept with the patient's hospital records. One can imagine that researchers are careful to file their copy of the signed consent form in case of any dispute. Participants presumably treat these forms very differently, some keeping them safe, others losing them or deliberately throwing them away. This, though, is beyond the remit of the committee. These exchanges of information and consent agreement remain in the imagination of the committee.

The Researchers

As well as using the submitted paperwork to review a research project, committees also sometimes invite researchers to attend the meeting to be interviewed by the committee. In this section I describe the conditions under which researchers are invited to meetings and the rationalisations members give for their attendance.

Most committees invite researchers to attend meetings under some conditions. My survey suggests only a handful of committees never see researchers (5.5%), with most seeing them occasionally (49%) or usually (45.5%). (No committee reported that it never sees researchers.) Not surprisingly, committees that invite researchers have meetings that last longer. Committees differ on their approach to inviting researchers. They either routinely invite the researchers to attend if they want to, or invite researchers if the chair of the committee or the lead reviewer think there is a problem with the application. One of the effects of standardisation foreseen by many committee members I interviewed was that researchers would be less likely to attend LREC meetings in the future. The new central allocation of applications to committees will mean that applications will be reviewed by committees geographically distant from where the research will take place making it less practical for researchers to attend the meetings. As a result the paperwork will become still more significant (Central Office for Research Ethics Committees, 2004). All of the members I interviewed thought this would be a loss.

The purpose of researchers attending meetings

It is interesting to reflect upon the purpose of researchers attending LREC meetings. In the ethical review of medical research the relationship between committees is primarily conducted through the circulation of paperwork. When researchers attend meetings it provides the committee with the opportunity to reflect on the limitations of the paper bound system. Furthermore, as geographers have emphasised, the question of distance is important to ethics (e.g. Smith, 1994). As LREC members' disappointment in falling researcher attendance shows, relationships conducted across distance are usually thought to be more morally perilous.

Researchers are allocated a time to be at the meeting. They generally sit outside the meeting room or wait in another room to be called into the meeting by the administrator when required. The committee discuss the application as usual (an introduction and first stage discussion). When the committee have come to an agreement about the main issues they want to ask the researcher

about the administrator will go and fetch the researcher. After the researcher has sat down the chair will introduce him- or herself; sometimes he (or she) will also introduce the rest of the committee. The chair then says something about the procedure (and something like 'we have discussed the research and feel there are a few issues we would like clarifying'). He/she then asks the researcher to take a few moments to explain the research to the committee, stressing that there are lay members on the committee and any explanation needs to be understandable to them. When the researcher has done so either the chair or one of the lead reviewers will open with questions for the researcher. Other members of the committee then begin either to stress points the lead reviewer has raised with the researcher or to make new points. The chair will eventually draw this discussion to close, thank the researcher for coming and explain that the committee will be in touch in writing.

A majority of committee members I interviewed felt that the main advantage of researchers attending was primarily procedural. It enables a quick clarification of any questions the committee has. For example, in one committee meeting I attended a piece of research reviewed involved patients, recovering from operations on their faces, wearing a mouthpiece to measure breathing rates. The committee were concerned this could be painful for these patients. The researcher, who was in attendance, was able to put their minds at rest by describing the mouthpiece and assuring them it would not be uncomfortable or painful. In interviews, members described the difficulty of understanding exactly what a researcher intended to do (the first stage of discussion described above). A few members felt this was because researchers were often sloppy in completing the paperwork. Most members, though, acknowledged the inherent difficulty of interpreting the paperwork about technically involved issues. Having the researcher present is an effective way to clarify what the research will entail. As a paediatrician on one committee told me when I asked him about the value of seeing the researcher:

> I think that you can pin people down if there is something contentious. You are always at the disadvantage when people explain themselves [on paper], that you are just going on what is in the protocol and you are then writing

> letters backwards and forwards for clarification. I think that there is a lot of value in researchers coming. C40

In interviews committee members often discuss the balancing of time constraints. Having researchers attend the meeting increases the length of the meeting but, they feel, also increases the focus and therefore cuts out a lot of wasted time. In a sense, members were expressing the view that face-to-face relationships require an initial time investment (the researcher arriving, introducing the committee, and listening to the researchers' account of the research). However, such interactions were rewarded with clarity and more robust decisions.

There is another, less common, rationale members offer for spending time meeting researchers, one that concerns the ability to make ethical judgements at a distance. A couple of members I interviewed felt very strongly that it was important to see researchers especially where they were unsure about what they saw on paper. They described this in terms of, for example, the need to look the researcher 'in the whites of their eyes' (C12) in order to judge their integrity and 'see if we trust them' (C23). This rationalisation is an interesting one because it is fundamentally spatial. The committee members are expressing a view that it is not possible, or less possible, to make ethical judgements at a distance. For these members, there is something inherently personal in these trusting relationships between researcher and LREC. This issue, of ethics requiring personal or local relationships, is one that I return to in chapter seven.

When this wasn't a member's first rationalisation I then asked whether having the researcher there enabled them to make better ethical judgements. Some members felt very strongly that it was no business of the committee to be making judgements about the integrity of the researchers. They felt the committee was there to ensure that the proper procedure had been followed. Others though, while not thinking their remit was to make a judgement about the character or motives of the researcher, recognised a subtlety in the evidence they drew on in making these decisions. When asked whether better judgements about applications can be made in person, the paediatrician quoted above said:

> If someone is hell bent on doing some poor quality research and not doing it ethically they are going to do it irrespective of what they have written down on paper and I don't think you can judge that. What you can judge from an interview with a researcher is sloppiness and sloppiness of thought. And the way they dismiss things. We have had situations where we have been interviewing somebody and they come out with a way casual comment: 'Oh, it doesn't matter how many blood samples you take'. Well, it does matter, it matters very much. You might get that sort of thing coming through. We have sent some projects back [for revision] because it has emerged from an interview that what is written on paper is not what they are going to do. C40

In effect, this man is pointing out that researchers can be competent at filling out application forms without necessarily conducting ethical research. If committees are able to interview researchers in person such gaps, he feels, are more likely to picked up.

Interviewing researchers also provides other indirect 'evidence' that LRECs draw on in their decision-making. In other words, while the committee uses interviewing a researcher to clarify issues, it can also involve assessing proxies for clarity too. In a couple of meetings I observed, junior researchers on a project attended ethics committees. On one occasion, the committee took that to signal that the principal investigator did not take ethics very seriously. It is usual for committees to take researchers' ability to perform well in the meeting as showing ethical credibility. For example, where a researcher did not seem too nervous, answered the questions asked directly and without contradicting her/himself, was able to describe the academic literature easily, these seemed to act as markers of a good researcher, and thus of an ethical researcher. Often committees will be reviewing research outside of their own specialisms so it is literally the performance, and not the substance of what is said, that is judged. For example, I asked a member of a committee how she assessed researchers whose work was outside of her own area of expertise. She replied:

> In those circumstances it depends on how convincingly the researchers defend themselves. If they are convincing then [we] accept their superior knowledge. We want to know that they have thought of a question and the possible effect on their application and that they can defend it. C45

In the next chapter I return to the relationship between ethics and scientific expertise highlighted in this answer. What comes across from these discussions about interviewing the researcher is not so much that committees understand the research any more than they did from the application form and research protocol alone but that they feel they can trust the researcher who appears competent. In this sense confidence becomes a proxy for ethical.

The paperwork that circulates between researchers and committee (application form, letters from the committee administrator, standard participant information sheet, and so on) constitutes the primary medium of their relationship. The reflections of LREC members on the value of having researchers attend the meeting shows the limits of these mediated distant relationships. Committee members feel that face-to-face relationships enable a better clarification of issues, and for some members, better and more moral decision-making.

The Committee members

Another important aspect of emplaced ethics is the particular people who come together in these places to discuss bioethics. An obvious omission in Bioethics is the embodiment of ethical actors, their gendered, able-bodied, racial bodies, and the pre-existing social relationships and identities thus invoked. Another aspect, the one I am going to concentrate on here, is the particular roles enacted in these spaces. I have already reflected on the setting of these committee meetings (health authority property), part of, but apart from, a working day. In a sense, this mirrors the role of LREC members.

LRECs are made up of both professional and lay members. These members of LRECs receive training in how to conduct ethical review; through their experience on committees they learn how to 'read' applications. Asked what LRECs do, members all answered in a similar vein: first and foremost protect patients from harm. The majority then said they are responsible for promoting good, high quality medical research. Their rationales invoke LRECs' Governance, a document most health professionals would not be so familiar with. LREC members understand ethical review in a particular way, in a way that most likely differs from researchers and the general public (Kent, 1997). Within the spaces of LRECs then members play particular roles.

LRECs are also, though, very much part of the working lives of health professionals. In chapter eight I address the role of lay members on the committees. In that chapter I argue there are a number of possible roles lay members could play but that in LRECs they are unable to play any of them effectively. The result is LRECs remain a primarily professional space. I want here to highlight the importance of the framing of issues as matters of professional expertise.

Figure 4.5 A committee member reading the paperwork

Members' reactions to Bioethics

One theme that can be seen as emerging from members' discussions of what they do is that it is not ethics. So, for example, one member had it that usually there is 'no real ethical meat' (C40). In stating that ethical review is not about ethics, committee members may appear to be taking a strange position. However, what they highlight is that the issues committees consider, if not the way in which they consider them, are not special or at all unusual ones for medical processionals. Members also describe what they do as not being concerned with Bioethics, the formalised academic discipline of Bioethics they are increasingly coming into contact with through LREC training.

These feelings that LRECs do not do (bio)ethics typifies a reaction of professionals to a potential threat to their professional autonomy. LRECs are a mechanism of self regulation. Although researchers must submit their research to the external scrutiny of LRECs, these committees are made up primarily of other medical professionals and medical researchers. The regulation is mediated through the structure and Governance of LRECs but it is still essentially self-regulation. The emergence of Academic Bioethics as an external rationality, with external expertise, poses a threat to professional autonomy and expertise in dealing with these 'ethical' issues. In one interview, one that I return to on the chapter examining the role of lay members on the committee, a consultant (and clinical researcher) who sits on a committee expressed a strong reaction to an Academic Bioethicist who sat on the same committee:

> I do not think having an ethicist on the committee has helped at all. The ethicist has been on the committee for six months now. We are not by and large dealing with moral dilemmas, and it leads to very prolonged discussion, often uninformed of any awareness of medicine or research...I have not found it useful, and on occasion found it intensely irritating. We had a ... guy resign from the committee, as there was a lot of drivel being spoken. You think you could be back at your desk working instead of listening to this, as you feel you are listening to the moral maze[8] or something. You are not dealing with projects which are likely to cause

[8] The Moral Maze is a radio programme on BBC Radio Four in which a panel discusses moral issues.

> serious harm. It is simple clinical research, so to have endless ethical discussions for the sake of it is wasted time. C19

Her view centres on the feeling that the issues committees deal with are of the type that medical professionals deal with in their everyday working life. Medical professionals and medical researchers then are the experts, she suggests. No others are needed.

On committees with no professional Bioethicist (only two of the twenty committees I attended as an observer had an Academic Bioethicist as a member), it is the training in bioethics to which members react. In a typical case, I asked a professional member what areas it was important to receive training in. He replied:

> I don't know really [laughs]. C27

I then made a couple of suggestions; perhaps committees need training in philosophical bioethics or research methodology? He then replied:

> You can train them in consent and things like that. I have been to many talks involving issues of purist stuff, but that does not impact on committee work. They are interesting but not necessary for committees. C27

Although this member found the 'purist stuff' of Academic Bioethics interesting, he does not believe it is actually helpful in reaching LREC decisions.

The relationships invoked by being a medical professional

A fundamental aspect of being a medical professional is the relationships it invokes. Doctors and nurses have duties both towards patients and each other. Key to the allegiances between professionals is the trust in others' expertise (and the established routes of dealing with unprofessional behaviour). What came through in interviews with professional members of committees was that LRECs

must work within and not counter to these commitments. Returning to the consultant who voiced her outrage about the Bioethicist, she described one exchange between them in the committee:

> We had a huge row with the ethicist on one occasion because he did not understand the science of the study. It was an exercise study on exercise on (a certain group of) patients, where you are doing treadmill studies and taking measurements. In doing that you need a stable baseline, so the patients have to come off their medication. These patients were all chosen by their consultants and the physiotherapists would have training, and he was up in arms that they could not come off their medication, and we had a row about that, because if you say that you would not be able to do any physiological studies. We argued that one fairly long and hard. It went through. You are saying to these people that not only can you not do this study, but any other like it. And you are saying to a consultant that he is not capable to make the decision of taking his patients off medication for six hours to take the study. This is not the role of the ethics committee. C19

It is not that this woman is necessarily arguing for a weak LREC. What she identifies is that health services simply cannot operate if professionals are not able to take decisions. There is a balance to be had between a professional's autonomy and accountability. This woman obviously felt that the Bioethicist on the committee had not got the balance right.

The issue of the relationship on the committees between professional and lay roles is one to which I will return to in chapter eight. It is clearly not a side issue to ethics proper. If we are to understand and improve bioethical decisions we must take the places and the social roles enacted therein as central. LRECs are comprised primarily of medical professionals who meet on NHS property to review medical research. Though the food and other rituals may help set it apart somewhat from the ordinary hustle and bustle of the NHS, this remains a thoroughly professional space where non-lay members continue to enact the roles of medical professionals whose duty is to protect patients from harm and respect the expertise of fellow professionals.

LRECs' emplaced bioethics

No one would expect the deliberations of LRECs to sound, on the face of it, like the more abstract reasoning of academic Bioethicists. It may be, however, that they are both structured in a similar way. LRECs go through stages in their discussion, first clarifying the relevant facts and identifying the ethical problems with the research and then settling on answers to those problems. Superficially this sounds much like the bioethical arguments presented in academic texts. I will argue, though, there are important differences between LRECs' and academic bioethical arguments.

The similarity or otherwise of LREC and academic Bioethics is important because it provides a first step in an analysis of the proper relationship between the two. Ethics committee members are increasingly being trained in academic Bioethics. Is an understanding of the theoretical defence of informed consent or even of academic ways of reasoning (what we might call philosophical methods) useful to committee members? Moreover, apposite differences begin to problematise the notion that academic Bioethics is, or should be, 'applied' in LREC practice. If we challenge a purely top-down (academic to practice) relationship we begin to open up the possibility of practice informing theory, in other words of a justifiable field of empirical bioethics.

There are at least three important differences between academic and LREC bioethical debate.

The framing of bioethics

The first substantial difference between academic and LRECs' bioethical discussion is the framing of debates. Academic Bioethics tends to be about crisis, whereas LRECs' bioethical discussion concerns routine, often procedural, decision-making. Each space, academic and LREC, works to frame the issues in certain ways, including some debates while excluding others. The issues addressed by Academic Bioethicists tend to be the 'big issues' facing society:

stem cell research, abortion, end-of-life, and so on. Moreover, these debates often render ethical discussion as being about crisis (Holmes, 2001). Questions are set at a point in time and space at which a series of events has become catastrophic, at the point where there are dilemmas. Usually, in such chains there are many preceding points at which action could have been taken, discussions could have been entered into that would have averted crisis. However, these small everyday decisions are less theoretically interesting (though they are more practically helpful). As a consequence of academic framing of Bioethical dilemmas the questions are often posed as stark moral choices, as either/or decisions (either the foetus' 'rights' or the pregnant women's). Crisis and stark moral choices, although they make more interesting theoretical problems, do not reflect the constant, smaller scale, incremental nature of ethics as most of us (including health professionals and researchers) experience it.

The questions LRECs debate are not chosen by them because they are interesting or morally difficult. LREC discuss the applications submitted to them. For her Master's dissertation Duckworth (2002) undertook discourse analysis of a couple of MREC meetings. She found that members took turns in assuming the role of different groups that would be involved in the research, researchers, patients, ward staff, and so on. During this turn taking they represented the different interests of these groups. I found no such turn taking in my own research. Rather committees assumed the role of outside professionals who balanced the strengths and weaknesses of the research. LRECs do discuss issues just as 'big', just as contentious, as those favoured by academic Bioethicists but they are framed very differently. Consequently, LRECs rarely address their subject matter as involving either crisis or either/or decision-making. LREC bioethical debate is about much more routine matters than academic debates.

Moreover, LREC bioethical discussions do not take place in a socially neutral space but a professional space (albeit mediated by the Governance). Each decision is made within the context of antecedent decisions, normal practice, and accepted professional ways of doing things. On the whole the LREC discussion could be characterised as aiming at the most ethical way of doing things. For example a researcher might want to interview people about their recent

experience of bereavement. So long as the researcher is credible, the committee may want to check when the interview will take place and where, that the researcher is clear that people are choosing to take part, and that there will be adequate provision for the interviewees should they get upset or change their mind about being interviewed. With the aim of the 'best way of doing things', LRECs balance a number of considerations: if a researcher has a lot of experience dealing with a particular patient group the committee are likely to be less demanding in other areas of the review; if a patient group is judged to be vulnerable, then the committee will be more demanding. LRECs may be spaces mediated by the Governance set out for them by the government, but they are thorough spaces of everyday professional decision-making.

The warrant of bioethics

A second difference between academic Bioethics and LRECs' bioethics concerns the role of reason and logic in settling bioethical discussion. Academic Bioethics is governed by reason, by the view that:

> 'moral norms are binding or prescriptive solely in virtue of their rational justification' (Hoffmaster quoted in Hedgecoe 2004:124).

In other words, a problem is settled in academic Bioethics when a logical argument has been given. Whatever the philosophical merits (or otherwise) of such warrant what is certain is that it bears little resemblance to how arguments or problems are settled in the world beyond philosophy departments. Indeed, as Gillet (2003) has noted the forensic logic and obsessive attention to detail brings to mind the reasoning of people with mental illness.

LRECs' bioethical discussions are not as logical and forensic as their academic counter-part. Rather than looking to internally logically valid answers, what settles LREC discussions is contingent and varied. Committees have a number of competing frameworks for assessing an application. Their primary formal purpose is to check that research meets the guidelines set out for them in

the Governance. Committees are also guided by their professional ethical codes and the understandings they develop in their working lives in the NHS. As I describe below, LRECs also include assessments of legality and social acceptability. Some sort of balance between these competing demands must be found (and within a limited timescale).

As a way of understanding the warrant of LREC decisions I was keen to explore with the chairs of committees how they handle conflict between different committee members' points of view. Based on the meetings I observed and the discussions I had with members, the normal settlement of a review is a consensus decision from the committee. All of the members I spoke to said their committee could take votes but few could remember it happening more than once, if at all.

One (lay) chair I interviewed felt that if there were to be a conflict where a member could not agree something because of their conscience he would not approve the application.

> If anyone feels strongly about (a problem) then I will not overrule one by nine. An objection is just as valuable even if the other nine have not seen it C38

He had never seen such a situation, however. Another (professional) chair emphasised 'society's norms' as a way of deciding.

> We haven't had anyone who just says: that's awful, when everybody else hasn't thought it was awful. I think that, we would have to have some discussion around what society's norms are. For example, if someone on the committee said: I think that abortion is dreadful and I don't think that we should be allowing this research. Then: is it legal? That would be the line that we draw, our benchmark. C3

Both chairs stressed they had never encountered any, what we might call, conflicts of conscience. As I have said above, I do not think that this is because

'big' ethical issues fail to come before LRECs. I observed the review of research on many ethically contentious issues: abortion, end of life, beginning of life, genetics, and so on. Rather, because of the framing of the debates as routine and professional, problems are encountered as procedural.

There is room for 'feelings' in LREC review. A member I interviewed reflected on her recent experience of academic Bioethics:

> I don't think that you can ever be entirely consistent (in LREC meetings). I have just started studying bioethics. It hadn't occurred to me before but if you read moral philosophy essays by very eminent people and they all have very very different outcomes in their arguments. So if that happens when they use a proper ethical framework to look at arguments it is going to happen in research ethics committees. Where people are often reliant on gut feeling: I wouldn't like that being done to me and so I wouldn't want it done to somebody else . C3

In this sense LRECs serve as an arena for the 'yuk' factor to be aired (Davies, forthcoming). These challenges to a piece of research do not however warrant a reason to reject a protocol but they do represent a challenge that must be answered. Sometimes this answer is a restatement of professional expertise. For example, in one review a couple of lay members reacted strongly to research that entailed participants being given morphine. This challenge was met with the response from professional members that this was normal, and the lay members concerns about addiction were assuaged. This reassurance then found its way into the participant information sheet. In another similar review on a different committee I saw a different outcome. The research being reviewed was gynaecological and involved an invasive procedure that was not normal practice. A nurse member said she thought it sounded like:

> an absolutely ghastly procedure, and they're all saying 'yeah yeah, that's all right'. And I'm thinking 'eee, there is <u>no</u> way I would want that to happen to me. C2

In this case the nurse and a (female) lay member managed successfully to argue that the research needed to include a 'patient experience' evaluation because, they argued, even if the operation was statistically or financially more successful the experience might be so unpleasant as to mitigate that benefit.

While a logical and reasoned answer 'settles' an academic Bioethical debate, LRECs settle debates by balancing different demands. No formula can be given for the warrant of LRECs' bioethics. At the end of the day, it is this group of people's collective decisions, their authority, that settles matters. Members work within a number of frameworks: LREC Governance, professional ethics and guidelines, feelings, potential 'crises of conscience'. Their situated and contingent decision making is very different from the hyper rational 'God's eye view' of the academic Bioethicist.

Revelation in bioethics

The third and final difference between the two types of bioethics concerns the attitude to transparency and revelation. In academic Bioethics the idea of revelation is key: by revealing the underlying principles at stake a problem can be understood and thus resolved. Through 'abstracting away' the embodied and emplaced 'context', academic Bioethics has it that an ethical problem can become knowable and indeed known. I call this the fallacy of transparency. LREC members do not, I argue, settle their debates by moving beyond the particular to the abstract but reason through the particulars: how well the forms presented to them have been filed in, how the committee as a whole understands the application. These sorts of inputs into decisions about bioethical issues aren't codified. There is no space for these sorts of considerations in Bioethical theory, which represents these decisions as having a purely rational nature. To understand LRECs' bioethics we must understand that the context of bioethical issues (the paperwork, the time constraints, the people) is not there to be 'seen through' to the 'real' issues.

Figure 4.6 A LREC discussing a point (papers in hand)

LRECs' bioethical discussions exhibit a number of characteristics that problematise the model of applied ethics. The framing of LRECs' debates is not about crisis and either-or decision-making. LRECs do address 'big' ethical questions (about the ends and beginning of life, stem cell research, genetics, and so on) but these are framed as professional and procedural. There is no either-or decision to be made but a careful balancing of the strengths and weaknesses. Furthermore, the role that logic and reason play in the warrant of LRECs' bioethics is reduced. Many things and people come together in the spaces of LRECs to make a bioethical decision. All must be considered when understanding the nature of LRECs' bioethics. We must avoid the fallacy of transparency. LRECs do not bracket off the particulars of the applications they review as epiphenomenal. They reason through these particulars.

Conclusion

In this chapter I have argued that ethics needs putting in its place, that to understand bioethics we need to produce empirical analysis of the spaces in which bioethical decisions are made. This does not, as many academic Bioethicists have it, lead to merely descriptive and therefore morally conservative ethics. If we are to understand and thus improve decision making about the ethical issues arising from medicine and bioscience we must move

from a model of applied ethics to thinking of emplaced ethics. The two modes of reasoning have different natures.

LRECs are spaces in which a group of people come together to ethically review proposed medical research. The committees are made up primarily of health professionals and meet on health authority property. As their reasoning shows, they are professional spaces. Committee members are therefore quite unwelcoming of academic or professional Bioethics, which they construe as external standards that threaten their professional autonomy. As a form of regulation, this is essentially self-regulation of medical professionals by medical professionals. The committee work is mediated by the Governance and standard forms issued by the government. We ought therefore to think of this as mediated self-regulation.

LRECs though are not just spaces of self-regulation. They are spaces in which scientific research is assessed. As such, LRECs are a mechanism for regulation of the relationship between science and society

Chapter 5

Ethics committees, not science committees

Introduction

While LRECs are, as I described in the last chapter, medical professional spaces, they are also spaces of science. Their remit does not concern the practice of medicine and health care in general, only of medical and health care research. Their Governance arrangements state:

> The primary task of a REC lies in the ethical review of research proposals and their supporting documents, with special attention given to the nature of any intervention and its safety for participants, to the informed consent process, documentation, and to the suitability and feasibility of the protocol. (Department of Health, 2001a: 9.7)[9]

With their remit to review the ethics of such research, LRECs provide an important site for the social (and spatial) study of science in action.

The title of the last chapter alluded to Livingstone's book *Putting Science in its Place* (2003). In the introduction he argues that it is the success of scientific knowledge in transcending the local that has discouraged study of the geographies of science:

> The suggestion that science has a geography goes against the grain. We can readily understand that there is a philosophy of science and a history of

[9] The Governance will hereafter be referred to simply as the Governance.

> science, even a sociology of science. But the idea of a geography of science runs counter to our intuition. (Livingstone, 2003: 1)

Despite this, as he clearly demonstrates, space does matter in the production, circulation, and consumption of scientific knowledge. As the allusion to his work suggests I wish to borrow his supposition for my own analysis of bioethics. Arguably, ethics has not been as 'successful' as science either at representing the world as spatially undifferentiated and placeless or at creating seemingly universal spaces such as laboratories, which enable the manipulation of the world as if it were placeless (although the ethico-legal project that is Human Rights is an obvious exception). Consequently, geographies of ethics are perhaps less counter-intuitive than those of science. After all we are used to thinking of different parts of the world having different belief systems. However, judging from the surprised and sometimes incredulous reactions I got from LREC members when I said I was a researcher from a geography department, perhaps the notion of geographies of ethics remains a challenging one.

What is clear is that the project of creating universal science requires a corollary project, that of the universalising of ethics. The very possibility of using humans in medical research (in the UK and beyond) relies on the ability to produce a standardised ethical subject and a standardised ethical review. The universalising projects of science and of ethics are, then, intrinsically linked.

That said, LRECs are constituted as ethics committees not 'science' committees. In this chapter I describe the work involved in the production of LREC reviews as solely ethical reviews. Although both the research ethics committee system and the field of Bioethics require a distinction be made between science and ethics, the distinctions committees make are contested and hard won. LRECs achieve, at best, a precarious pulling apart of the two subjects. If we 'put ethics in its place' we conduct empirical investigation of ethics as emplaced, such as this investigation of LRECs. Rather than begging the question and assuming facts and values are dichotomous, an ethnographically informed empirical study of bioethics shows that it is only through practice- the practice of

LRECs- that they are cleaved apart, to produce a purification of ethics from science. In this chapter I describe the distinction LRECs make between science and ethics, between facts and values. These distinctions are not given, but are precarious social achievements. As Gieryn (1995) has described, the distinction between science and non-science does not lie in any essentialist difference as the likes of Popper, Kuhn, or Merton would have it, but in contested and pragmatic demarcation which 'occurs as people contend for, legitimate, or challenge the cogitative authority of science – and the credibility, prestige, power, and material resources that attend such a privileged position' (405). As gatekeepers to research 'resources', such as patients, equipment, and staff time, LRECs engage in, what Gieryn calls, the boundary work of science. As he says:

> But what is "science"? Nothing but a space, one that acquires its authority precisely from and through episodic negotiations of its flexible and contingent borders and territories. (Gieryn, 1995: 405)

However, for LRECs the authority of their boundary work rests on carving out spaces of non-science. As ethics committees, according to their Governance, they are only able to address ethical issues.

Although there is some obscurity LRECs are not supposed to be engaged in scientific assessment of research. This, as I describe below, is an impossibility and the requirement to perform a strictly ethical review is a constant tension for LRECs. Although they would never use such terms, committees recognise both the heterogeneous and hybrid ethico-scientific nature of the decisions they must make and that they must re-inscribe the purity of these two realms, casting their judgements as strictly ethical and non-scientific. In this chapter, I describe the hybridity of science and ethics as LRECs experience it. I then turn to what Latour (1993) calls the work of purification and examine how LRECs re-inscribe the very fact value dichotomy that their actual deliberations so promiscuously violate.

The Governance and LRECs interpretation of it

One of the requirements for a 'favourable opinion' (approval) set out in the Governance concerns the 'scientific design and conduct' of the research (9.13). LRECs need to 'be adequately reassured' of, amongst other aspects:

> The appropriateness of the study design in relation to the objectives of the study, the statistical methodology, and the potential for reaching sound conclusions with the smallest number of research participants (9.13a)
>
> the justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants, other present and future patients, and concerned communities (9.13b)

While the Governance requires ethical review to include 'reassurance' of these things, it does not require LRECs to review them themselves. Most organisations funding research, such as the MRC, will conduct a peer review of the scientific merit of proposed research. Evidence of a positive outcome of such a review would allow LRECs to be reassured of the scientific merit without actually having to make any assessments themselves. I feel sure this is how the system is designed to operate. The system, though, is designed with large research council or pharmaceutical company funded research projects in mind. LRECs by their very nature also review small localised projects most of which are not externally funded and therefore not peer reviewed. In these cases it is not clear, to LREC members at least, what 'reassurance' of a scientific review means.

There is some ambiguity in the minds of LRECs whether the Governance countenances a scientific assessment of research as part of a LREC review (if one has not already been conducted). It seems LRECs have been told they are not allowed to review scientific issues, because that is 'not their job' (C6). Over the period of time I conducted my fieldwork, it became more clear that the Central Office of Research Ethics Committees (COREC) intended for LREC (and MRECs) to interpret the Governance as requiring an external scientific peer review. When I sought clarification on the issue from the COREC I was told that

it is the responsibility of the sponsor of the research to ensure a research was peer reviewed. The sponsor should submit referee comments with the application form. Where there had been no such review LRECs could ask for the research project to be resubmitted with evidence of a peer review or could arrange their own external scientific assessment of research (Central Office for Research Ethics Committees, 2005). This answer actually clarifies very little. It states that LRECs can demand a peer review be undertaken but not the conditions under which they should.

Informants in my research were confused about what an ethical review that did not include scientific issues might be. As with the member who reported that scientific review was not the job of LRECs, many committee members reported both that the Governance forbids them to conduct a scientific assessment and also that scientific concerns are very important in an ethical review of medical research. The chair of a committee I interviewed read the Governance as ambiguous. I observed a meeting of the committee she chaired and it seemed to me that she was more than prepared to let the committee include assessments of methods in their review. I asked her how a scientific review of protocols fitted in with an ethical review. She answered:

> We do have a problem with science review, as the research governance document contradicts itself. On the one hand it says ethics committees should be concerned about ethics, not science which should be left to independent reviewers. On the other hand it says, the ethics committee needs to assure itself that the science of the project is good. We do struggle with that as we see a lot of student projects. The science is so appalling that we have to give it time in the review. For instance, experienced researchers coming from another discipline did not have science as we know it, and they also did not have the ethics either. We do look at the science, and if that is not right, the project is not ethical. We are not in a position to say it has had such and such a review, by a university department, so we won't look at that. We are not confident yet, as experience shows you can have high quality researchers and their science is flawed. We do not get that many MRC proposals, when we do we think this is funded and has been through a peer review process, and we shall call a halt to that discussion. We think

> this is the way it is being funded, so we shall concentrate on the other sections. C19

Her answer is quite confused reflecting the confused position she finds herself in. At either end of the spectrum, poorly written student research and MRC sponsored trials she feels confident about what attitude she can justifiably take. There is, however, a large grey area in the middle where committees must exercise considerable discretion. In light of this ambiguity, many committee members interpret the Governance to mean that they are probably responsible for conducting a scientific review. I asked committee members what issues their committees look out for in reviewing research. This answer, from a professional committee member, is typical:

> We have categories, the science of the project, how they treat the participants, the quality of the supervision (we see a lot of student research), is the documentation user friendly? As a researcher I look at the science of the project primarily. Having read the GAfREC regulations, it seems we are responsible for ensuring the science being of a very high quality. C16

In her response she describes an uncertainty about whether GAfREC, the Governance, requires LRECs to conduct a scientific review. It seems to require it, she says. As I argue below it matters that many members of committees are active researchers. She gives her answer 'as a researcher...'. Whatever the stipulations of the Governance, she sits on the committee as a researcher. Performing that role on an LREC is not too dissimilar to performing it on a scientific peer review. There are differences to be sure, but they are of degree, not kind.

While many of the committee members I interviewed raised the importance of scientific issues in ethical review, few reflected on the implications for LREC membership. Implicit in many of the answers committee members gave was the issue of how specialised LRECs must be to perform their ethico-scientific review. This issue was brought up explicitly in one of the last interviews I conducted, with a committee member who was an active researcher:

> The big question is should ethics committees review the science or just stick to the ethics and I believe that the two are integrated. You can't have a project that is ethically good if the science is bad. Very simple things like if the sample size is in no way adequate then you can't answer the question so you are putting people through unnecessary…you are giving people the false idea that if they take part in the research it will lead to such and such a result but the study size is too small so it won't so that it is unethical. Therefore you have to know something about the design of the study and the science of it. So I tend to think that ethics committees should do both. There is a separate move, at least here, to get things peer reviewed separately and to get documentation saying this has been peer reviewed and these are the peer review comments and all that comes to the ethics committee. Personally I think that that is another layer of bureaucracy which is another hurdle for researchers and if you had an ethics committee who could manage that [scientific review] it would be better. C45

Her answer highlights that if ethics committees are to review scientific aspects of research they need to have the right skills to do so. The Governance does require that some members of the committee are practicing scientists (6.4) and that committees have statisticians (6.4). The question of how much scientific expertise committees would need to conduct such a review seems likely to remain unanswered as the independent scientific assessment, that 'other layer of bureaucracy', becomes policy.

Ethico-scientific hybridity

Whether ethics and science are conceptually separable or not, in practice they are very difficult to think of in isolation. In other words, even if the Governance requires one, a purely ethical review is difficult to carry out. The ethical issues that arise from any particular research project obviously depend on what the research is and how the researcher has approached the design and conduct of the research. A research hypothesis can be more or less credible, more or less likely to produce results that advance knowledge in that area. The less credible a hypothesis is, arguably, the less ethical it is to ask people to partake in

the research. Whether or not they are asked to give their flesh and blood, subjects do invest time and expectations in research. Health authorities, too, invest staff time and resources in research. The reverse is also true. It is unethical to waste resources, time, and emotion on research that will only confirm already accepted facts. Assessment of the credibility of a hypothesis depends on a reading of the existing scientific knowledge in the area. Moreover, however credible a hypothesis is, a badly designed piece of research that will not achieve its aims is unethical. Some assessments involve independent measures, such statistical ones, while others require knowledge of the research area. On the whole evaluations of methods are paradigm and specialism specific. For example, although randomised controlled trials need to be subjected to statistical analysis, qualitative research has a different warrant. Additionally, it would be a minimal evaluation of research methods that did not include a consideration of the strengths and weaknesses of past research methods on similar projects.

The issue of the relationship between science and ethical review was one the committee members I interviewed returned to again and again. In one example I asked a lay member whether her committee had similar opinions about the ethical issues raised by the applications the committee saw. She answered:

> We have never not come to a consensus. Sometimes we chew it over for a really long time, taking an hour on one protocol. In the end you give and take a bit. People do have firm opinions on certain things. One of our members has very firm opinions on a good research hypothesis and making the research match the hypothesis. Now we are not allowed to alter the research. That is not our job. We are only allowed to look at it to see if it is ethically sound. But poor research in itself is unethical. So if it really is poor, really poor, you just have to say 'I am sorry but you [researcher] are going to have to look at it again. C6

Questions of whether a research hypothesis is a 'good one' and whether the research 'matches' the hypothesis or is able to answer it, are thoroughly embedded in the 'science' of research. Her answer also highlights the expectations of the members of the committee in shaping the relationship of science to ethics. Some of the members of each committee are, after all, research

scientists (37% are clinical researchers, with a further 28% conducting research on human subjects). Indeed they are on the committees because they are research scientists. It is therefore not surprising they should have 'firm opinions' about good research and should include these in their assessment of applications. Her reply suggests both an understanding that ethical review ought not to include consideration of scientific questions but also that it must: 'poor research in itself is unethical'. Her answer also points to the ability of committees to work with these two irreconcilable demands and, albeit through lengthy discussion, come to a resolution.

Committee members certainly felt an assessment of scientific validity is an inescapable aspect of ethical review. However, unless a researcher lied on their application form about the 'science' of the project, it is difficult for LRECs to reject applications on the grounds of poor science. I asked a consultant member of an LREC if her committee often had disagreements about the scientific merit of research. She said that one member of her committee raised such issues a lot:

> [One member] does that a lot, and I have done it [too]. It was good that I was late actually, as one of the earlier proposals I was not comfortable with....People from the same department can point out complications to a procedure. [The chair] would stop a study on the basis of that. If the researcher is ill informed or is telling porkies to the committee, we do not want the trial to go ahead. C13

There is no suggestion that this member stayed away from the meeting in order not to have to comment on an application she thought was 'bad science'. There is a definite relief though. In her answer she says that an application would be rejected if there were complications with a procedure. Presumably she means if a researcher had left that information out of their application. However as seemed to be the case with the application she did not want to review, most disputes about science concern disagreement rather than fraudulent or 'ill informed' researchers.

I observed a very interesting example of such debate at one committee meeting. A committee member tried to have a project rejected because he thought it represented 'bad science'. Although the research method was sound the hypothesis being tested was not one he thought worth testing. The committee were reviewing an application for a randomised controlled trial to examine whether acupuncture could be used to control asthma. Randomised controlled trials, or RCTs, are the scientific gold standard for medical research. This RCT was well designed: it tested a null hypothesis, was statistically sound, and had clearly defined and objective outcome measures. Although the committee passed the research (with changes to the participant information sheet) the discussion it had highlighted the inherently negotiated nature of the designation 'good science'. The lead reviewer was a (medical) consultant. He said he thought that acupuncture was hocus-pocus and the chart of acupuncture points that accompanied the application 'a load of rubbish' a vestige from before there was knowledge of anatomy proper. What was interesting in his assessment of the project was that the valid scientific design of the project did not confer an assessment of good science because he did not believe the hypothesis was worth testing. He went on to say that although one of the problems with 'this kind of thing' is that they are never tested and therefore never disproved, this researcher obviously believed acupuncture worked and therefore was in danger of biasing the results. Some of the committee members challenged the lead reviewer, telling him 'not to be so closed minded' and that 'given the alternatives, this is worth a try'. Although the intervention, acupuncture, was minor the committee spent much time discussing the risks the research involved, the health and safety implications, and the recruitment of patients. It seems likely that their unease emanated, not from these more ethical issues directly, but from the 'scientific' aspects of the trial. In the end, the LREC passed the application but required changes be made to how the research was explained in the participant information sheet. The chair signalled the end of discussion by saying what was important was the quality of the research design, not whether the committee 'knew' what the outcome of the research would be. This challenge to scientific aspects of the research was settled with recourse to science. The LREC's discussion also shows how doubt about one aspect of an application, say science,

leads to a more exacting review in other areas, for example health and safety or patient recruitment.

Although LRECs do not routinely review complimentary therapy such as the project described above, they are often called upon to review qualitative research and many LREC members are clearly unsympathetic to the 'scientific' credibility of such research. Quite a lot of LREC members I interviewed expressed a feeling that qualitative research isn't really research proper. (A view I found quite interesting as these members were taking an hour or so to take part in qualitative research.). In interviews such observations were often accompanied by remarks such as: 'It is not really research but it is not going to harm anyone'. The implication was that qualitative research would be passed with a less rigorous review than 'proper' research. In actual fact, however, this is not how committees behaved. Committees often felt far more able to suggest changes to qualitative data collection methods than they did with other research. Furthermore, they were much more protective of staff time when it came to administering these types of data collection methods. There are, of course, defenders of qualitative research on LRECs, but they tend not to be the consultants. A nurse member who had sat on a different LREC, ten years earlier, said that on that committee any application that wasn't quantative and lead by a consultant tended to get dismissed outright (C7). She thought that this was less likely to happen now, something she attributed to the attitude of the new chair.

Other committees view qualitative research as non-comparable with clinical research because of the difference in the risks that are entailed. Indeed, one of the LRECs I observed did not discuss qualitative research at their meetings but dealt with it at a subcommittee. The chair explained the potential harm was just of a different magnitude than drug trials and the like, and as a result it just did not warrant a full committee review.

The tension-ridden scientific assessments of research by LRECs raise issues of the paradigm and specialism specificity of 'good science'. The chair who was unsure about how to deal with the grey area between MRC funded research and student projects, quoted above, says:

> For instance, experienced researchers coming from another discipline did not have science as we know it, and they also did not have the ethics either. We do look at the science, and if that is not right, the project is not ethical. We are not in a position to say it has had such and such a review, by a university department, so we won't look at that. We are not confident yet, as experience shows you can have high quality researchers and their science is flawed. C19

The researchers from other disciplines she mentions were applicants at the meeting I attended. Although they were university academics they were from a discipline where research in hospitals is unusual. The committee had not seen research like it before, and it seems likely these researchers had not made an LREC application before either. Her comment, that 'they did not have science as we know it, and they did not have the ethics either' is fascinating. It not only shows the paradigm specific nature both of methods and the language used to explain them but also the extent to which researchers must learn the skills of explaining their 'science' and their 'ethics' to ethics committees. In this example the LREC asked the researchers to find a collaborator who was used to working in hospital settings. The question of research specialism is a point I return to in the conclusion of the thesis. A recent report suggests that COREC ought to create a post of 'Scientific Officer' to deal with those applications that have not had a scientific review. The details are not clearly laid out but the notion of a central 'Science Officer' seems to ignore the specialism specific nature of 'good science'.

The work of purification

Although LRECs assessments of applications include both ethical and scientific assessments, LRECs are ethics committees and not science committees. Their formal jurisdiction does not extend beyond an ethical review of research protocols. While LRECs cannot maintain a crisp distinction between ethics and science during their own deliberation, they must do so when they represent their

discussions to the external world. In this sense, LRECs are implicated in what Latour (1993: 11) calls the 'modern critical stance'.

The purification of the hybrid review into the distinct realms of ethics and science occurs, to a large extent, beyond the committee meeting. Committees do remind themselves, or more likely are reminded by their administrator, that their discussion is going beyond their formal remit. However, there is space in their closed and confidential meeting for co-existence and contradiction. However, this space does not extend to the accounts LRECs must give of their decisions to the world in general and to researchers in particular. These accounts, such as the letters administrators write to researchers reporting the committees' findings, were outside the empirical window of this research. I doubt, in fact, that I would have been able to negotiate access to such documents. However, the initial oversight was a misinformed presumption on my part about the places where the 'work' on the committee takes place. Despite this empirical blind spot, it is clear from my research that LRECs employ a number of strategies in their work of purification.

Respecting professional judgement

One strategy LRECs use to deal with the tension of 'only reviewing the ethics' is to respect research scientists' professional judgements. Researchers may feel that LRECs question their judgements too often. However, there are many more questions about the science of research that do not find their way into LREC decisions because a researcher is able to give an adequate performance of expertise.

When a committee member disagrees with a scientific assessment in an application, my observations suggest it is likely the LREC will ask the researchers to defend the positions they have taken. In a typical example, in one meeting the committee discussion of an application had centred on the validity of the science of an application. I asked a committee member I spoke to about this. He said:

So there were major concerns with whether the techniques being used would give you an answer. That has come up on a number of other occasions and is a particularly difficult one, particularly if it is coming from a group of good researchers, who one assumes know their stuff, and assume they wouldn't want to be doing it if they thought it would not give meaningful results. Occasionally someone with specialist knowledge in that area [on the committee] will take issue. If they feel strongly about that then we ask the committee member to discuss it with the researchers and then we look at it again. C14

Although LRECs might seek such assurances from researchers, as I argued in the previous chapter, without a specialist on the committee there is no substantive way to judge the researchers' reply, apart from as a rhetorical performance of expertise.

As LRECs are unable to reject an application on the grounds that it is 'bad science', and even if they could they may very well lack specialists who could make such assessments, LRECs must be satisfied with performances of expertise from the researchers. For example, in one meeting I attended questions arose about a patient quality of life questionnaire that was to be used during research. Part of the questionnaire asked about patients' feelings before and after an operation. One of the committee members felt the questionnaire was badly designed. Her concerns centred on there being no provable cause between a change in feelings and the operation. She said a person might be feeling depressed because his wife has left him not because he is waiting for an operation. The researcher was at the meeting and the committee member spent a lot of time criticising the validity of the questionnaire. In the end though the researcher's robust defence won out. I asked another member about how the exchange was resolved and whether the committee member gave up in the end. The committee member replied:

> Yes. I think that [in the end] she could just understand the point of the researcher. The researcher had done it for valid reasons although that wasn't obvious from the [application] form and that is why it is good to have the researcher in [the meeting] so that we can find that out. Otherwise we have

to send a huge letter out. And its backwards and forwards. C7

I was sure the committee member had not come round to the researcher's way of seeing things. She remained convinced the method was unable to establish a causal relationship between the operation and the patients' moods. However, she was not prepared to call for it to be rejected on these grounds and, if she had, it is unlikely her committee would have agreed with her. The committee could not reject the project based on this dispute about the methodology of the research. The matter was settled through a performance of expertise. The researcher was able to engage with the committee's questions, quote other research findings that employed similar methods, and seem confident. These proxies come to stand as a mark of sound scientific research. In the absence of both a mandate for substantive review of the science and the specialist expertise required, that performance of expertise is all the committees have to go on.

The harm of bad science

A second strategy for purifying their hybrid reviews is to treat unscientific research as a relative rather than an absolute harm. Strictly speaking, research that will not yield results is unethical even if it does not cause any other discomfort or harm to participants (Foster, 2001). Bad science is, on this reading, an absolute harm. Participants agree to take part in research with the implicit understanding that there is the possibility of the sum total of knowledge being increased. If there is no such possibility participants have been enrolled under false pretences. Even if no other harm has been inflicted on them subjects have, on this absolutist reading, been harmed.

Although committee members feel that unscientific research is unethical in itself, they tend, in meetings to make judgements about it as a relative harm. Committees may be unconvinced that a particular proposal will yield results, but so long as it not deviate much from normal treatment committees tend to be less concerned. As members told me so often when we discussed qualitative research: 'Its not scientific but it won't hurt anyone'.

Protecting resources

Another way LRECs' remit of ethical review can be cast is as a protection of research resources. It is important make sure patients' time is not wasted out of respect for them. But it also important that suitable patient-subjects, along with staff and equipment time, are not 'wasted' on poor research projects. As gatekeepers in the research process, LRECs inevitably make some decisions concerning the delineation of worthwhile science from bad or pseudo-science.

The boundary work LRECs perform as gatekeepers of research 'resources' is not an explicit remit for LRECs, but it is an inevitable one. Affiliations, such as members' commitments to particular methodologies or research areas, can be thought of as potential conflicts of scientific interest. In the case of the acupuncture RCT, the consultant failed to enforce his version of the boundary between science and pseudo-science. However, his judgement meant that the application received a much more thorough review that it otherwise would have. As LRECs are constituted as ethics, and not science, committees their boundary work between science and bad science is an indirect one. However, the relationship between science and ethics is difficult and contradictory.

Re-writing the participant information sheet

Some issues arising from committees' difficulties with the boundary between science and ethics are settled by recourse to the patient information sheet that LRECs consider as part of their review. In their review of this information sheet, LRECs make judgements, not about science, but about the communication of science. For example, research committees often have scientific problems with student research. Such research must have ethical approval, just like any other research, but the smaller time scales, budgets, and inexperience of the researcher often mean the project is unlikely to yield useable (publishable) results. However, conducting research is an essential part of student training. LREC settle the dilemma by making sure the participant information sheet for the research states that the research is part of a degree:

> We try to treat it no differently to other research that is proposed. But we are sympathetic to time deadlines, so we would let things go through in smaller numbers than normal to fulfil a masters or an MPhil where they have a year to do it. As long as they say it is a pilot study, and do not make over exaggerated claims as to what it can change, we would accept. C19

Whether or not patients understand the meaning of student research in the same way as LRECs do is an important question. But it is not one I ever heard committees ask. Similarly, because of the nature of LRECs, they are sent small pilot projects by established researchers. Committees understand pilot research to mean research not designed to produce results directly but to test out the feasibility of a strategy or research method without necessarily leading to a further scientifically valid study. Often LRECs require a participant information sheet to state that the research is pilot research. Again, whether patients understand this to mean the same thing as LRECs do is an apposite question.

Informed consent and the displacement of responsibility

Informed consent constitutes an important mechanism in the social achievement of the fact-value dichotomy, by which LRECs can perform an ethical, but not a scientific, review. So long as the research is not judged to be harmful in other ways, LRECs pass unscientific research as long the participant information sheet makes mention of its 'unscientific' nature.

For example, one committee I observed reviewed research that involved cancer treatment. Patients would be given additional drugs before the removal of a tumour, as well as the normal post-operative drug regime. Some members of the committee felt this research was not good research, that it was testing an improbable hypothesis. Moreover, the additional doses of drugs might even be harmful to patients. Other members felt patients would be offered hope by the research (more drugs sooner must be better), which was illusory. I asked a member of the committee how the committee's doubts about this research were settled. She said:

I think everyone agreed it was non therapeutic, and it would not be detrimental to the patient as they would be going onto these drugs after surgery anyway. So perhaps we were wondering slightly in the back of our minds that it might be beneficially therapeutic that nobody knew about. And providing the patient information sheet was absolutely clear you were doing this as a guinea pig, completely altruistically with no benefit then that is entirely left to their own decision. C13

Issues of scientific validity, coercion of patients, harm inflicted by false hope or prolonged drug use all factored in the discussion the LREC had of the application. It was though informed consent, or more specifically participant information sheets, the committee used to settle the ethical issues. What they did in this way was pass the responsibility for protecting the patient back onto the patient.

Spatial quarantine: Humans as objects, objects as subjects

Another strategy of purification also concerns informed consent. As I describe in the next chapter, informed consent is central to LREC review. The principle serves a number of purposes, not least the legal protection of the researcher. What is interesting, though, is the how the logic of consent and the consent process enables participants to be conceptualised on either side of the nature/human binary. LRECs require that consent is obtained prior to a participant's involvement in research, ideally 24 hours prior. In order to consent to participation a person is engaged as a rational human subject. Having consented the subject <u>then</u> becomes a natural object open to the scientist's gaze. The participant can withdraw their consent to being treated as an object of research and in doing so revert back to being a human subject. Just as the existence of ethics committees separate ethical issues from scientific ones, so informed consent separates off ethics from science. By taking ethical research to be primarily concerning consent, LREC review renders participants either/or rather than both/and: either human, moral, rational or natural, passive, object. A

distinction is made between the time and space of ethics and science which resists the requirement of a hybrid ontology of both/and.

Bioethics is often said to have emerged in response to the ways in which science and technology are now ushering in a post-human or post-natural world in which genetic modification and human enhancement (Rose, 2001) make a mockery of the Cartesian certainties of old. These technologies pose new ethical questions, to be sure, but in philosophical terms Bioethics actually represents a very traditional response to them, that re-inscribes Enlightenment metaphysics. An account of the emplaced bioethics of LRECs exposes the nonsense of the binaries fundamental to academic Bioethics. Participants in medical research are not natural objects, whatever that might mean. Even on the most conservative reading, on a reading faithful to Enlightenment principles, participants in medical research are persons. To be a person is to be a moral being, to be a rational being, to be capable of knowledge, beliefs and desires. Such an acknowledgement has lead many to argue for relational ethics (Whatmore, 1997). However, the ethical subjectivity in which LRECs are implicated knows no such hybridity: that which is studied is rendered as objects, out there in the world. The scientist is a disembodied subject who gazes, classifies, and thereby knows the world. This is an Enlightenment metaphysics of human vs nature (Inwood, 1995).

While it might be that we have never been modern, we still need to account for the persistence of such dichotomies in so much of our politics (Edge, 1995: 18). Globalising medical research markets requires LRECs and their role in the production of a universal subject. Moreover, this mechanism for purifying science and ethics is not merely a useful (for some) slight of theoretical hand. It has effects. If biomedicine has remoulded the subject, promising a post-natural world of 'enhanced humanity' (Silverman and Bloor, 1997, Rose, 2001), so too has the ethical review of medical research. LRECs are implicated in the production of a particular ethical subjectivity, calculating, individualised, and consenting.

Conclusion

The notion of emplaced ethics problematises one of the fundamental tenets of philosophical ethics. The impact of an analytic distinction between facts and values cannot be over emphasised in the academic field of Bioethics. There is, it is argued, a logical distinction to be made between facts and values (Foot, 1995). From this 'logical gap' between descriptive and prescriptive statements it follows that no 'ought' statement can be derived from an 'is'. For example, that people do, in actual fact, eat animals has no bearing on whether it is morally right to do so. Many feel that this logical distinction can be 'over dramatised', that it merely challenges us to give an adequate account of the relationship (Hepburn, 1995). Despite such readings, the distinction has huge impact on the way in which bioethical issues have been addressed (Borry et al., 2005). It has been assumed that empirical analysis of the way in which ethical issues are, in fact, discussed and settled in actual practice can tell us little or nothing about the way they ought to be. These are issues for theoretical and not empirical analysis.

By their very existence LRECs make a de facto distinction between scientific and ethical issues that draws on this fact-value dichotomy. Science is the study of the world, of what is, and ethics of what ought to be. Ethical issues might arise in the process of undertaking scientific research but they are reviewed by Research Ethics Committees. Such a prescription assumes these ethical issues and the science are separable, both conceptually and spatially. They can be understood and assessed when decontextualised from their scientific genesis. Indeed, they can be understood and assessed by people unable to make other (scientific) types of assessment about the same piece of scientific research. That there are LRECs, on the one hand, and peer review on the other, both assumes a fact-value dichotomy and, in turn, reinforces that dichotomy by assessing the ethics in a different time, place, and institutional context from scientific peer review of the research. LREC practice, then, seems to re-confirm the two domains of reasoning, of 'is' and 'ought', are separable.

The fact-value dichotomy, though, is a distinction made between concepts. The real world is inevitably a lot messier than the theoretical lines we draw in the sand. Science, as empirical investigation, is both partial and value laden. Ulrich Beck (1992: 29) is only the latest in a long line of social theorists to insist that science is 'reliant on social and thus prescribed expectations and values such that [s]cience's rationality claim to be able to investigate [the world] objectively permanently refutes itself.' But the same is true of Ethics. Ethics too must be informed as much by what is the case as what ought to be (Hedgecoe, 2004).

An important consequence of 'putting ethics in its place', that is studying ethics empirically, is to problematise where the proper place of ethics is. By their very existence ethics committees create a kind of spatial quarantine of the ethical issues arising from medical research. Informed consent serves as a mechanism for transforming ethical subjects into scientific objects. As such LRECs help re-inscribe the binary through another space-time quarantine.

One of the consequences of studying ethics as emplaced is to disrupt the categories of ethics and science. Ethics committees, like much of our politics, assume a distinction can be made between ethics and science. Indeed, a distinction can be made. It is not one that follows 'naturally' from a logical dichotomy though. It is a hard won social achievement. Spatial quarantining of ethics might seem to neatly address the need for an ethical review of medical research. We might do better though with a system that recognises the messy ontology of the world rather than retreats to logic.

Chapter 6

Informed consent: from ethics to accountability

> A kind of administrative objectivity is created whose logic is to standardize, which prefers rules over unfettered judgment and which hides its processes of selection.
>
> (Power, 1997: 95)

Introduction

In this chapter I argue that ethical review exhibits a drive for the sort of 'administrative objectivity' described above in the epigraph. Fundamental to the construction of this very particular kind of objectivity is informed consent. Informed consent has come to dominate ethical review because it has been successfully standardised in the participant information sheets and consent forms LRECs review. These documents seem to offer a means of reviewing and thereby controlling yet-to-happen exchanges between patient and doctor. Consent forms have been developed to record, decontextualise, and circulate a 'consent'; to make it mobile and provide the potential to mobilise it (for example in a law court). In this way, the participant information sheets and consent forms serve as 'immutable mobiles' (Latour, 1988) that can circulate between different sites involved in the practice and regulation of medical research as evidence of its ethical soundness. Participant information sheets and consent forms create the appearance of 'openness' and 'transparency' by providing artefacts that could be examined by people interested in the 'consent' the patient gave. Thus the immutable mobility an 'informed consent' serves not only, as I showed in the last chapter, to effect the spatio-temporal separation of an anticipatory ethical review

of a project from the subsequent conduct of the science proper, but also, as I show in this chapter, to regulate science.

The qualities that make informed consent standardisable are fundamental to the success of ethical review as regulation. Attention to LRECs and their understandings and practices of informed consent shows how they forefront the sheets of paper in front of them on their desks. Their obsession with the details of the participant information sheet and consent form may seem a far cry from the high ideals of Bioethics. We should be careful, however, not to read this as a failure by LRECs to understand what is meant by informed consent. Academic Bioethics may stress the self-evident good of the autonomous authorisation enshrined in an informed consent but informed consent persists beyond Bioethicists' offices. In the spaces of LRECs, it is the legal and the regulatory standards that define what is meant by informed consent. Consent, as it has evolved in this context, promises an administratively reliable objectivity to replace fickle professional judgements. Faced with criticism from researchers and the pharmaceutical industry about the cost and burden of ethical review, and from the public about the ethics of medical research, standardisation is one strategy for deterring and deflecting criticism.

Another effect of such standardisation is to reduce bioethical problems to problems of consent documentation. To explain how that reduction comes about, I begin by describing the Governance's emphasis on consent documentation and the limits of its other prescriptions. I then turn to the demands of accountability placed on LRECs and how these produce informed consent as a solution to other ethical problems. My central argument in this chapter is that increased scrutiny of LRECs leads committees to stress the more standardised, rule-governed aspects of their review. I describe how this new emphasis on accountability and openness has lead LRECs to concentrate on their review of informed consent documentation. In turn, this has resulted in a reification of standards, a narrow focus on the grammar of participant information sheets, and a paternalist conception of informed consent. I argue that in order to understand LRECs deliberation we need to examine their role, and the role of informed consent in particular, in wider networks of scientific regulation.

Bioethics[10] as consent documentation

The emphasis LREC members place on the importance of consent, and the framing of it in terms of the paperwork involved, reflects and is shaped by the prescriptions of their Governance arrangements[11] (Department of Health, 2001a). The informed consent process, as the Governance calls it, figures centrally in how the Governance describes the role of research ethics committees (REC) in ethical review. It states:

> The primary task of a REC lies in the ethical review of research proposals and their supporting documents, with special attention given to the nature of any intervention and its safety for participants, to the informed consent, process, documentation, and to the suitability and feasibility of the protocol.
>
> 9.7

Informed consent, in this prescription, is central but it does not have precedence over other issues such as harm and scientific merit. In the last chapter I described LRECs' treatment of science. It is through the practice of LREC review that 'informed consent' comes to dominate these primary tasks. The inadaptability of these other regulatory precepts, preventing harm and ensuring good science, to anticipatory ethical review leave the floor open to consent.

The demands of being accountable

My own research is part of wider demands made on LRECs to be 'accountable' to the outside world. I was, after all, literally asking members to give an account of their activities. It is telling, then, that informed consent figured highly in the accounts members gave of what LRECs do. When I asked committee members what they look for when reviewing applications the issue of

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[10] To recap, the term 'bioethics' is used to denote the ethical problems arising from biological and medical research. I also include ethical issues arising from other health service research in the use of the term, such issues might not be included in the literal meaning of bioethics. I use the term 'Academic Bioethics' to denote the study of these issues by academics, characterised by abstract and logical assessments of bioethical problems.

[11] Hereafter, referred to as the Governance.

consent was always among the first to be mentioned. I asked a nurse member of a committee what makes research ethical. She replied:

> What makes research ethical? Well the bottom line is that the patient must not be harmed. And they must be fully aware of what is going on and give their consent to it. … I think that is the bottom line really. C2

Answering the same question a member of another committee, a retired GP, said:

> Consent. That seems to be the most outstanding matter now a days. In legal terms, at any rate you can consent to anything, can refuse treatment for a good reason, bad reason or no reason at all. C37

These answers are absolutely typical. In their accounts given to the outside world, in this case to a social scientist investigating LREC practice, consent is given centre stage. In some sense this reflects what committee members (quite realistically) expect outsiders to be interested in. It also reflects their experiences of conducting ethical review.

Informed consent, for LREC members, is not an abstract principle but takes a particular material reality: the consent documentation. This is so in their review and their accounts of it. For example, when I asked one member, a retired statistician, what he looked for in an application, he gave this very typical response:

> Well, obviously if the methodology is that relatively sound. It doesn't have to be perfect but …Information sheets: I am very hot on information sheets and consent forms; that patients aren't pressured. And the confidentiality of the general information about patients. Those are the things that I tend to jump on. Particularly with patients being given time to make their decision. C5

There is a feeling of relief in this gentleman 'jumping on' certain aspects of the review, such as the participant information sheet. Similarly, many committee members, including a practicing clinical researcher I interviewed, observed that there is clear guidance on what needs to be included in participant information. It is LRECs' role to ensure researchers write them in line with the guidance. She said:

> We start off at the beginning, about how people are identified? How people are chosen to be approached? First identification, then approach, and then documentation. You get fed up saying it, as usual the documentation is appalling. C18

Members' responses indicate a need to crystallise the difficult and slippery issues of medical ethics into a few more manageable issues amenable to review.

The retreat to standards

The Governance requires LRECs be able to justify the decisions they make. It states:

> The REC should always be able to demonstrate that it has acted reasonably in reaching a particular decision. When research proposals are rejected by the REC, the reasons for that decision should be made available to the applicant. 7.9

In the face of such demands, LRECs tend to stress the rule-bound nature of the review they conduct. For example, I was discussing training with one committee member and was interested in exploring what it means to be trained in ethics. She stated very clearly that ethical review was procedural:

> We do not make moral judgements, as we have to have arguments for our decisions. You cannot do that any more, you have to itemise your objections. C13

In particular, standards are clearly an important way of justifying their decisions to researchers refused permission to proceed with their work. A nurse member expressed a typical opinion when she described how researchers sometimes react to her committee's decisions:

> Some of them do react that anybody could have the temerity to criticise the proposal. Problems are more easily dealt with if GAfREC guidelines are quoted. C16

In the face of the actual, or potential, requirement to 'itemise' objections to research, it is not surprising that committees concentrate on areas of ethical review where there are standards to implement.

It is not only the Governance that has the potential to hold LRECs accountable for their decisions. Talking to LREC members, I found a palpable insecurity about their position vis-a-vis legal responsibility. Talking about the experience of sitting on an LREC, a researcher said:

> [It has become] more formalised and more accountable. It used to be something that was low profile, people doing out of good will and in their own time. ..... We are still in a situation where the accountability is not very clear. And all we have got is more bureaucracy. ..
>
> It will be interesting to see what happens with this Wakefield MMR business because there have been calls to interview all the members of the ethics committee who approved that project. And take them to task. Never been a situation where an ethics committee member or chair has been sued for approving research that was later judged to be unethical. One suspects that that may happen in future and that will be when people start thinking about accountability. There may have been some attempt to clarify that through research governance and so on but it is not terribly clear to me. What has happened COREC has made a big impact on... I am sure they would say trying to harmonize the whole thing, standardised so that it is not so whimsical, putting a lot of control over it all. There are advantages and disadvantages to that and I am a bit cynical about it. [Some people think]

> that these are people purporting to act on behalf of the public and people taking part in research without people actually doing that. Probably beefing up the importance of committees without any consideration of what they are actually doing. C45

Although there have been huge changes to the regulatory system they are, as yet, untested in law courts or General Medical Council professional misconduct hearings.

In this context, members forefront the guidance and standards in their conceptualisations of consent. The guidance on the participant information sheet and consent form is, after all, the most standardised area of ethical review. While LRECs are a mechanism for holding researchers accountable, LRECs in their turn might also be held accountable for the decisions they make. Indeed, as I noted in chapter three, medical researchers and the pharmaceutical industry that funds them have long complained bitterly the ethical review system. Standards offer LREC members a feeling of certainty and security in their decision making in what can sometimes be an otherwise insecure role. A chair of a committee, a medical professional, illustrates this in her answer to a question about whether her committee had a check list it used in reviewing applications. She answered:

> Fairly loosely, we look to see if the science is reasonable, whether the application is adequately completed, the issues around the consent form, issues around the patient information sheet, and then there are issues, its much more woolly, whether research is actually ethical. I mean the science can be perfect but if you are doing something to people that is not acceptable then it is not going to get through an ethics committee. So those are the things that we look through. I mean we don't have a check list that we tick off. Basically the guidance in the cream coloured folder [which the Department of Health issued for research ethics committees]. C3

Bioethical issues can seem 'woolly' and standards something to be 'jumped on'. Making sure the researchers apply standards and implement guidance offer a secure role. As a lay member on a committee put it:

> It appears to me that most researchers are not aware of what the rules are and if they get it right it is because they have used guidance and most of them don't. It is pretty easy to get it wrong. C36

Ethical issues are after all 'woolly'. They are dilemmas we, as individuals or as a society, do not know how to solve. If there were an answer to a dilemma it would cease to be an ethical issue. Ethics has room for ambiguity and different ethical judgements (Edwards et al., 2004). In a regulatory system such as LREC review, though, where the creation of standards has received so much attention, it is more difficult to exercise discretion.

Of all of the prescriptions made in the Governance informed consent then has come to dominate ethical review. Consent, as it is performed through ethical review, forefronts the standard participant information sheet and consent form that researchers need to replicate. As I discuss below, requirements about participant information sheets are often utilised to 'solve' other ethical problems.

Informed consent as a solution to other problems

As I argued in the previous chapter, informed consent is central is LRECs' work of purification. By requiring researchers to re-write participant information sheets LRECs are able to review the ethics of an application (the communication of science) but not the science. Informed consent, or more particularly the acutely standardised participant information sheets, become the de facto answer to other issues facing LRECs.

A further set of ethical issues that informed consent is used to settle concerns social justice and institutional racism. As I describe in more detail in chapter seven, British public services have recently been under strong criticism for institutionalised racism (Blofeld, December 2003, MacPherson, February 1999). These issues are addressed in the area of the review where LRECs are able to exercise power. A recurrent problem LRECs have with research is that the participant information sheets and consent forms have not been translated

into other languages. No doubt such translation is an important part of making research accessible to all. However, it is only one aspect. There is confusion within LRECs between race and language. As a black researcher, at a meeting I attended, told an all white LREC, plenty of black people can speak English. The translation of participant information sheets is, though, an aspect that LRECs can legitimately influence. As such, it is used to address their remit, as part of the NHS, of inclusion.

Informed consent is central to ethical research as it is understood and practiced by LRECs. These committees though do not understand bioethics as the academic Bioethicists do. The emphasis placed on the need for accountability in the regulatory process means that 'woolly' ethics needs to be made standard, concrete, and material. Those ethical prescriptions that cannot become so are neglected in LREC review.

Standard participant information sheets and consent forms

The guidance COREC offers concerning participant information sheets and consent forms is the most standardised aspect of ethical review. According to the Governance, LRECs must satisfy themselves with the account they have been given of the consent process (9.17a) and the 'the adequacy, completeness and understandability of written and oral information to be given to the research participants' (9.17b). Although both written and oral information is mentioned, it is the written information that lends itself most easily to LREC review. The practicalities of an anticipatory review make it almost impossible to assess all but the most standardised script for an oral presentation of information. I never witnessed such a review in any of the meetings I observed. Instead the discussion in LREC meeting focuses exclusively on the written information.

The existence of the template for the consent documentation leads to an emphasis in the review on whether the participant information sheets and consent forms meet this standard. So for example, when I asked a medical consultant who sat on a committee what he looked for in the information sheet, he said:

We try to encourage a standard, and it has been getting better over the past couple of years. So we actually provide a guideline as to how it should be constructed, so that they do not miss things out. We want it to be aimed at the right level, as some can be far too technical and some are far too simple. We want it to be honest and include things like the standard indemnity clause, about what will happen if people are harmed, which researchers do not like to say, but we say you have to say that as we like you [the researcher] to be open with people and honest. C14

Similarly, a lay member on a different committee stresses the importance of pitching the information at the right level but also of implementing standards. I asked her what she was looking for when she read applications.

The consent form, information form. First and foremost I look at those. [A Colleague] who is also a lay member, his pet thing is consent forms and information. I invariably look at it but I know that he will raise it. [What is important] depends on the research it is covering. If research where the people going to be involved have disabilities then you look for the names of the people doing the research. Contact numbers, details, headed notepaper: which is always more professional than anything else, the drop out clause. [The patient needs to] know why it is necessary and what's actually going to be done. Whether or not you think that they can actually understand the words or not it needs to be brought down to layman terms. And explained, so they know what's being done. C44

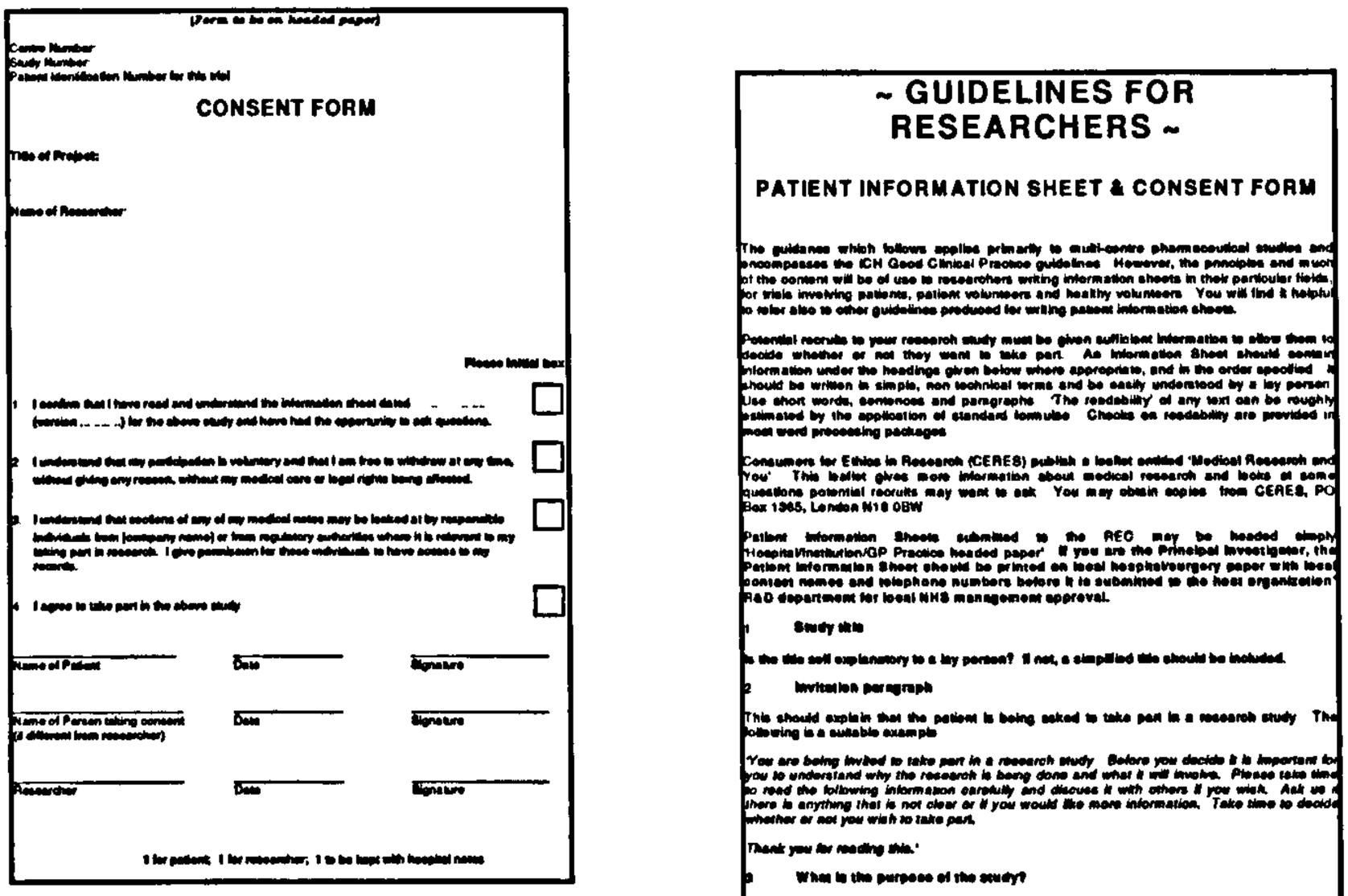
Patient information sheets need to be based on the template form. They need to be formatted according to the template: headed notepaper, a format of questions and answers, standard information, version number, date, and so on. These are not irrelevances. They are central to LREC review, and applications that fail to conform to those standards are returned for revision until they do.

Participant information sheets from the researcher's perspective

My own research fell under the NHS research Governance as I was using NHS staff as informants and the observations took place on NHS premises. A

committee I approached very early on in the research said it would be prepared to take part in the research but only if I wrote a participant information sheet. The requirement in itself is interesting. I was, after all, conducting research of the type that these committees exist to review. Their own Governance stated that my research ought not to have taken place without ethics committee approval. I did not have ethics committee approval. What I did have though was a participant information sheet.

In order to create a participant information sheet I, like other researchers, had to go to the COREC website and download the standard participant information sheet.



(Form to be on headed paper)

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Title of Project:

Name of Researcher:

Please initial box

1 I confirm that I have read and understand the information sheet dated .. .. .. (version .. .. ..) for the above study and have had the opportunity to ask questions.

2 I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3 I understand that sections of any of my medical notes may be looked at by responsible individuals from (company name) or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

4 I agree to take part in the above study

Name of Patient	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

1 for patient; 1 for researcher; 1 to be kept with hospital notes

~ GUIDELINES FOR RESEARCHERS ~

PATIENT INFORMATION SHEET & CONSENT FORM

The guidance which follows applies primarily to multi-centre pharmaceutical studies and encompasses the ICH Good Clinical Practice guidelines. However, the principles and much of the content will be of use to researchers writing information sheets in their particular fields, for trials involving patients, patient volunteers and healthy volunteers. You will find it helpful to refer also to other guidelines produced for writing patient information sheets.

Potential recruits to your research study must be given sufficient information to allow them to decide whether or not they want to take part. An Information Sheet should contain information under the headings given below where appropriate, and in the order specified. It should be written in simple, non technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs. 'The readability' of any text can be roughly estimated by the application of standard formulae. Checks on readability are provided in most word processing packages.

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You'. This leaflet gives more information about medical research and looks at some questions potential recruits may want to ask. You may obtain copies from CERES, PO Box 1365, London N16 0BW.

Patient Information Sheets submitted to the REC may be headed simply 'Hospital/Institution/GP Practice headed paper'. If you are the Principal Investigator, the Patient Information Sheet should be printed on local hospital/surgery paper with local contact names and telephone numbers before it is submitted to the host organization's R&D department for local NHS management approval.

1 Study title

Is the title self explanatory to a lay person? If not, a simplified title should be included.

2 Invitation paragraph

This should explain that the patient is being asked to take part in a research study. The following is a suitable example:

'You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.'

3 What is the purpose of the study?

The background and aim of the study should be given here. Also mention the duration of the study.

Figure 6.1 Standard Consent form and Page 1 of Standard Participant information sheet (Central Office for Research Ethics Committees, 2001)

Having downloaded these forms I then set about creating my own information sheet. The template lists questions which researchers should use to structure their participant information sheet. Questions such as 'Do I have to take part in this research?' are accompanied by a standard response:

> It is up to you to decide whether or not to take part..... (Central Office for Research Ethics Committees, 2001)

Other questions such as 'Why have I been chosen?' have guidance on the information researchers need to include, such as how many participants will be enrolled in the research project. As I had been sitting on an LREC for a year or so at the point I wrote my participant information sheet, I had an advantage over most researchers completing the same process. I was nervous though the first time I gave the information sheets to committee members. Sure enough, within five minutes a (lay) committee member had spotted a grammatical error. (It has been changed in the version reproduced here!).

I found that I had very mixed feelings about the requirement to produce standardised forms. I used them a lot while I was recruiting committees and members. I found it helpful to have a summary of the research that I could send out to people. That it was in a format that the people who received it recognised obviously made them feel comfortable. On the other hand, much of the text seemed superfluous. For example, I was required to tell readers to take their time when deciding to take part. I also found other aspects, such as having to provide a telephone number, awkward. Many committees do not like mobile phone numbers to be provided because they are expensive to call. I did not really want to give out my mobile number before I had been in contact with people anyway. As I was working between home and a shared PhD office I had to choose which number to provide on the information sheet. I choose the shared office even though I was only there half the time and couldn't be sure that when I was out of the office messages would be taken. I would have much preferred to keep my initial contact through email or writing and then taken informants' telephone numbers and called them. The standard forms though did not give me this choice. Maybe my preference was too researcher focused and I was not thinking of the research experience from the potential participant's point of view. However, I cannot see that there is anything inherently ethical about giving people a number they are only quite likely to make contact with you on.

INFORMED CONSENT

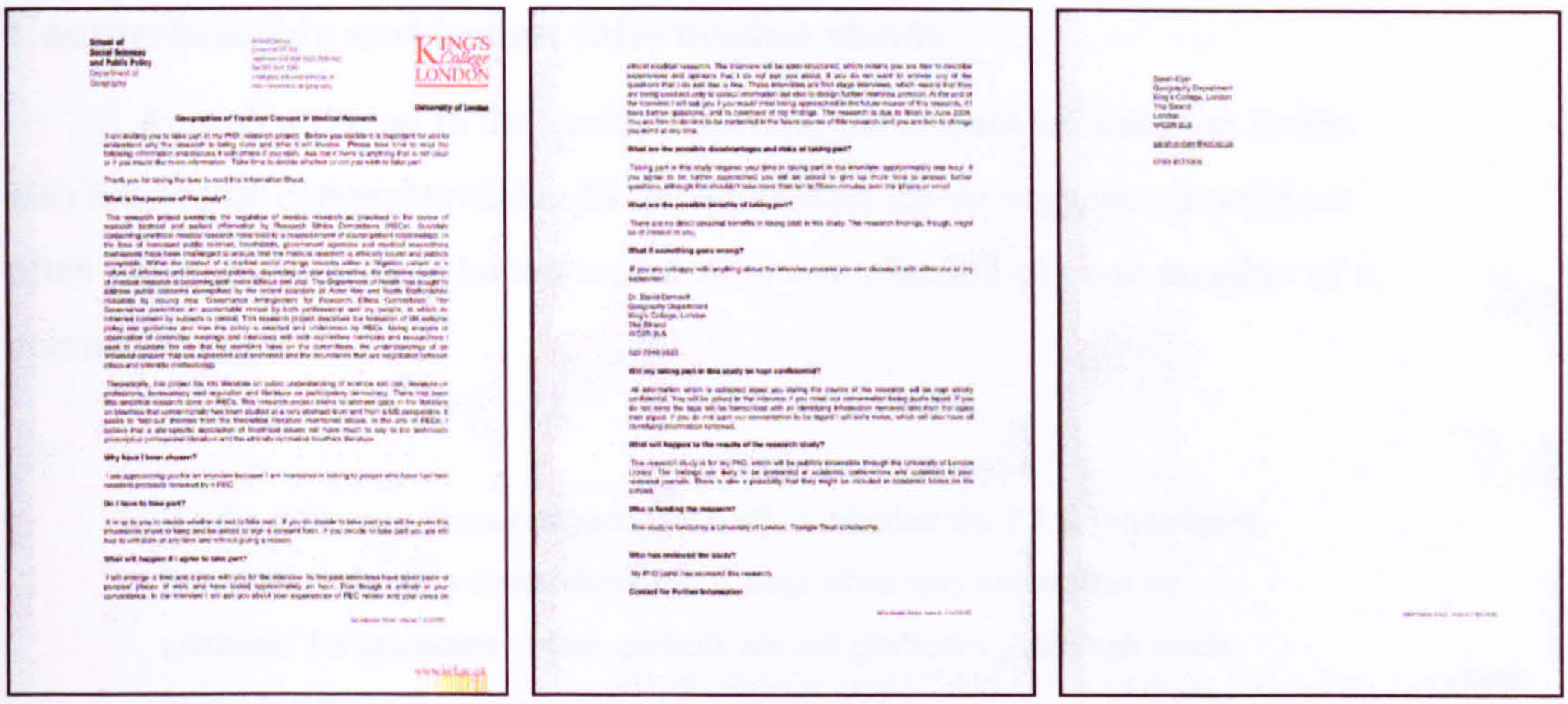


Figure 6.2 My participant information sheet

See Appendix 7

I was able to use the participant information sheet I had written without ethical review. For other researchers, though, their participant information sheet would have to be reviewed by an LREC before it could be circulated to potential participants. Researchers would submit the information sheet and consent form along with their application.

My own experience of writing a participant information sheet was mixed. It was clear to me that LREC members felt reassured by me having produced information in the standard format. It was one they were familiar with. This made me feel less anxious about approaching members. Of course, most people approached to take part in LREC approved research would not be familiar with the standard participant information sheet format. For the researcher, though, there is something very reassuring about knowing that you have followed standard procedure. On the other hand, I also felt that the standard form was overly prescriptive. Some of the questions forced me to conduct my research in a certain way. I found this frustrating. These are only my own experiences of participant information sheets. Further research is needed on the way researchers understand, respond to, and implement these important materials.

Comprehensible and honest information sheets

As well as being in the standard format, participant information sheets also need to be comprehensible. As the quotations above suggest, committees often judge the writing to be too technical or complicated. As one member of a committee put it:

> So the difference [between good and bad] is whether the P.I.S. [participant information sheet] is comprehensible. I mean often they are written by graduates for graduates. Many patients are not graduates. Although much graduate writing is very good it is too complicated. C34

As this committee member suggests many of the amendments required by LRECs arise because the information sheets are judged to use language that is too difficult for most people to understand easily. LRECs want participant information sheets with short sentences made up of words with few syllables. Committee have various rules of thumb they use to assess whether information sheets are likely to be too testing for participants. One committee chair I spoke to asked researchers to use the readability function on their computer (C3). One member told me that information sheets need to be accessible to people with a reading age ten or eleven or to a reader of *The Sun* (C12).

A common complaint from committees is that participant information sheets are difficult to understand because they contain medical terms or otherwise assume a background medical knowledge. For example, I observed meetings where committees required researchers to remove particular words or phrases such as 'psychosocial' or 'I.V.' (intravenous). At other times committees required that sections or whole information sheets that read 'like a medical text book' be re-written and re-submitted.

Committees often required researchers to make changes on participant information sheets to make them more accurate, more 'open and honest' (C14). Some such judgements are easier to account for than others.

The judgement that a participant information sheet was not accurate enough was often made through a comparison with the application form and research protocol. As this member said:

> I check patient information sheet first, [to get] a nice simple idea of what is going on. Then I will go back to the rest [of the protocol] and find out what is actually going on and deal with the rest. No, I probably first I read the objectives and then come back and read the patient information sheet.
>
> **C27**

Whatever the order he reads the documents, the information needs to accurately reflect what is written in the application form and research protocol. In one meeting I observed, for example, a researcher had submitted a participant information sheet that said 'access to this information is restricted'. In the application form, though, it said who the information would be accessed by (positions not names). The committee required the researcher to add that qualification to the participant information sheet.

Judging honesty or accurateness of information, particularly information about risk and uncertainty, is a often a subjective and highly politicised matter (Renn et al., 1995, Beck, 1992). Small changes in the wording of participant information sheets can make big differences to the way risks are received. In one review of a participant information sheet, for example, a committee required the statement 'this research might be of some benefit to you', to be changed to 'we do not know if this research will be of benefit to you'. The content of these statements is very similar. Their sense is not. In one meeting I observed a committee required researchers, who had said in their application that a certain procedure had a 1/100,000 risk of death, to say so on the participant information sheet. The same committee required another researcher to remove a numerical measure of exposure to radiation and replace it with a comparison. It was argued that the measurement of radon was incomprehensible to lay people. I asked a member of the committee about these two decisions. She said:

> It's a different thing. The 1/10 000 risk is of a defined event whereas the radiation we are talking about a generally increased risk of cancer. I suppose that you could say that of any cancer but I think that it would be very difficult to quantify. C45

One committee member said that the participant information sheet should express the radiation exposure (and consequent risk) as equivalent to chest X-rays. Another committee member answered that it was equivalent to 9,000 such X-rays and that they would have to use trans-Atlantic flights as a comparison so as not to scare patients.

The communication of scientific information and in particular of uncertainty to non-scientists is fraught with difficulties. LRECs are part of a process of 'administrative objectivity'. The proliferation of standards makes it appear that no judgement is involved in assessments about the honesty of the information sheets. That is just not the case.

Although lay members do not have expertise in risk communication, members would mention in interviews the importance of lay members in assessing the participant information sheets. One such member, an actor, said she left the medical aspects of the application to the health professionals on the committee:

> One of the things that I look at is the patient information sheet, the participant information sheet and the consent form and if I can't understand it then I really think that other people may not understand it although they know their medical condition better than I do. C6

As the lay member quoted above (C44) suggests there is a feeling amongst lay members (I am not sure this is shared by medical professionals) that lay members have something special to contribute to the review of the participant information sheet. The rationale goes that professional members of the committee are not able to look at a participant information sheet from the patients' perspective. I describe this role of 'proxy patients' in more detail in chapter eight and argue

that it is not an effective role for lay members to play on committees. It is worth noting here though that the profile of most lay members is very different from the population as a whole. Lay members are, not least, much better educated than most, with 78% of lay members being educated to at least degree level and 41% having a higher degree.

As often as not, the complaints LRECs make about information sheets are about mistakes in grammar, spelling, and typographical errors as they are about technical languages. The lay member quoted above went on to say:

> Unfortunately what we are not allowed to do is proof read for them and correct their grammar and spelling mistakes. [But] if the grammar really makes it nonsense then we say so. C6

Although this particular committee had taken the decision not to act as proofreaders for researchers, most other committees I observed effectively do so.

> I mean we, they, get so picky. You know: there ought to be a comma between this and that. I mean some of the stuff that you get to read is just, you wonder if any of these people ever went to school. The way they write. Just appalling. C2

Examples of changes I have seen committees request include 'medial' be corrected to 'medical', 'affect' to 'effect', 'as' to 'has', 'the questionnaire will be read to you by myself' to 'I will read the questionnaire to you'. In marked contrast to the high principles emphasised by Bioethical theorising, these sorts of considerations are the everyday stuff of LRECs' deliberations on informed consent.

The reification of standards

Committee members themselves highlighted how researchers can reify standards and apply them without consideration for context. Committee members

often described the balance they must strike in their review of participant information sheets and consent forms, checking standards have been met but also assessing the appropriateness of the document to the particular research participants. A researcher who sat on one committee said:

> Many have not put themselves in the position of the research participant. I would say that is our overarching thought, as the researchers are so involved in their process, that they do not stop and think how is it for Mrs Bloggs or Mr Smith. Sometimes, older people over 85 will be given documents which are ten point [font and] closely typed. Some participants have cognitive impairments, and sometimes a nice word will make a child feel more involved in the research. C18

A very common example of such a problem was that participant information sheets and consent forms replicated the template too exactly and did not remove irrelevant text. The standard consent form, for example, includes a clause about consent to access medical records. Often this was left in the research consent form whether or not the research included accessing notes. As a committee member explained:

> One problem that we have with the standard form is that it always says hospital notes on it. Patients see 'hospital notes' and say 'what do you mean?' because a lot of these deal with people who are either ill or elderly and who are perhaps not particularly well educated. It tends to freak them. Some of the forms that aren't tailored say things like 'I agree that you may look at my medical notes' when they aren't and why would they have that in there? [Researchers are] getting agreement to do something that is not in the protocol. C36

Committee members recognise that the standardisation of LREC review and, in particular, the template 'consent documentation' can lead to difficulties.

Committee members themselves, though, are often guilty of a reifying standards. A telling example concerns the amount of time patients have to read

the participant information sheet before they consent (or otherwise) to take part in the research. There is a question in the standard application form, that asks:

> How long will the participant have to decide whether to take part in the research? (If under 24hours, please justify) (Department of Health, 2003: question B16)

As conversation with committee members revealed this question is often answered by researchers with 'at least twenty-four hours'. LRECs are usually quite satisfied with such an answer. I asked a consultant about the issue of timing. She said:

> They should be given at least 24 hours, longer if it is something difficult, but it is not always practical. But for me, the question then can be, how much effort has the researcher gone to get this information to the patient? I mean if you are going to wait for somebody to have a heart attack and then after that you look for consent then you are not going to have a lot of time, like the one where they asked to take samples of blood from patients who have just had a heart attack. With them there is no question of giving them 24 hours (to decide) because they need treatment. If your research is worthwhile and has to be done before treatment then ok. But there was that one about shocking people during fibrillation, and there was plainly not going to be any attempt to contact people in advance. If there are good reasons for the researcher not to give 24 hours notice then fine, but if it is because the researcher cannot be bothered to contact the patient in advance then we cant have that. C13

In her answer, as with committees' practice, the 24 hour minimum has become the exclusive issue. She outlines how in research on critical issues, such as heart attacks, it will be impossible to give a patient 24 hours to decide whether or not to participate in research. In these cases, if the research is worthwhile, the minimum time requirement can be overridden. In other cases, a researcher may ask for the minimum to be waived with no real reason. The difference between 'at least 24 hours' and a week, say, is huge, especially, when we might want

participants to discuss research with their family or GP. So long as the standard is met, though, no real scrutiny has to take place.

LREC members' views of participant information sheets

Given the centrality of participant information sheets to LREC discussions, it is important to reflect on how members themselves rationalise the decisions they make about the consent documentation. I asked committee members about particular incidents where, it seemed to me, a participant information sheet had been given a lot of attention in the meetings. I was keen to explore the extent to which spelling mistakes, non-headed notepaper, and so on are, strictly speaking, unethical. The members I spoke to offered three different conceptualisations of the significance of participant information sheets.

The first characterisation members gave concerned manners. The importance of well-presented participant information sheets and consent forms derives from the need to treat people as though they matter. To present potential participants with sloppy paper work is rude. I asked a nurse member who put forward this notion whether manners were important in ethical review. She answered:

> My committee is very down on that. If the tone of the letter is not correct we will change it. You cannot say participation on the study is practically voluntary, or a similar phrase. I think when you see an application, you can see how the applicant views the participant. In a way [LRECs] are saying to them, 'do not think about patients as fodder for your research. This is a human being with a complete set of rights, and if they give you consent you are very lucky. Just because you work for a research institution or are a doctor, it does not mean that people have to take part in your study'. I think that was a deeply held attitude in the medical profession, and there has been a revolution over the past few years in the way that we think about patients. And there is going to be a further revolution where the future patient is not going to look like the past patient, who was grateful and would say 'ok doctor', and ask for advice, and generally be a lot more compliant. In future patients will have a more developed set of expectations of what they want

> from the NHS. They will look for nurses and doctors to help them through the system. I think that general cultural change...Ethics and treatment are fundamental to this revolution. C16

For this member, manners are an important aspect of ethics. Other members, though, did not think that manners were ethics per se, but that they were nevertheless an important difference that ethics committees could make to patients' experiences of research.

Those members who stressed the importance of manners tended to describe the review as a case of thinking about patients' feelings, as well as accuracy. At times, for example, committees required that researchers re-write and re-submit information sheets because they were patronising, brusque, or rude. At other times committees asked researchers to re-phrase statements that they felt, although honest, were upsetting. One committee asked a researcher to remove 'this doesn't mean you have cancer' from an information sheet. I asked a member on this committee why they had made that decision. He answered that the committee had decided that it was an insensitive way of expressing information (C39). In another example, a member of another committee said they had asked a researcher to remove 'the side effect profile is as yet unknown' from a participant information sheet because it would have 'put the fear of God into me' (C10).

The second rationalisation that members gave concerned the reputation and standing of the NHS. Members argued that patients would not make a distinction between research and the NHS more generally. In 'hosting' research the NHS had a right to check that nothing would happen during the research that might bring the NHS into disrepute. This included sloppy, untidy, or badly written information sheets. As one lay member described:

> [I check] contact numbers, details, headed notepaper: which is always more professional than anything else C44

A professional member on another committee betrayed some frustration about this assumed role of his committee. He said that although the proof reading of participant information sheets and so on was useful, in the sense that it prevents patients thinking badly of the NHS, it is really not the job of the LREC. Rather it is the researchers' responsibility (C40).

The third and final rationalisation for the emphasis on the consent documentation was by far the most commonly given one. In the mind of many LREC members, the participant information sheets serves not only as a prima facie reason for rejecting research (or asking for amendments), it also acts as a proxy for not taking ethics seriously. As the nurse quoted above said, 'you can see how the applicant views the participant' (C16). Another member put it this way:

> If researchers don't care enough about the patient to write a decent P.I.S then we ought to be worried. It means that we will look at everything more closely C23

For these committee members it is not just that ethical research requires well-written participant information sheets per se. The documentation members have in front of them is the only means they have for evaluating research and researchers. Far from 'abstracting away' the particulars of a case to reveal the underlying principles at stake, members take the particulars to stand for wider issues. The material, the consent forms and participant information sheets, is not irrelevant to ethical decision-making. It is at its crux.

Figure 6.3 The ever present paperwork

These rationales of the importance of participant information sheets are interesting but what they fail to acknowledge is that LRECs concentrate on the implementation of standards because, simply enough, that is their job. LRECs do not exist in isolation but as part of a wider system for regulating science.

Informed consent as a boundary object

I have argued throughout this thesis for the importance of the embodied and emplaced understanding of LRECs in making sense of their ethical decisions. The spaces in which ethical discussion happens cannot, I argue, be 'abstracted away' but must be taken as fundamental to any analysis. As soon as we start thinking of one such space, though, it begins to pose questions about other related spaces. How do researchers and participants understand informed consent? What about politicians and the civil servants who write LREC Governance? How is it understood in the media and by those who read about scandal of medical research conducted without 'informed consent? Our analysis of LRECs must attend to these other sites, which impinge upon the space of the LREC review in various ways.

Informed consent mediates many relationships other than the researcher-researched, albeit indirectly. It serves as a way of translating meanings and agendas between different social worlds. A country's ability to host medical

research rests not only on adequate scientific facilities and expertise, but also on an atmosphere of public acceptance and trust. Moreover, the existence of scientific facilities and expertises themselves depend on companies and scientists having faith in a place as 'research friendly', a place worth investing time and monies in. Nowhere are these issues more pertinent than in medicine which requires, not only general public and political acceptance, but also patients willing to become human guinea-pigs. 'Informed consent' has become a successful cipher within these complex networks of dependence across different social worlds.

More specifically, other sites present themselves in LREC meetings and in committee members' conceptualisations. Committee members, for example, sometimes invoke the Governance or professional guidelines to help settle a disagreement in a meeting. I have also observed meetings where members suggest how a proposed decision might be interpreted in court or in the local press. In interviews members have mused on the difference between an informed consent in law and ethics, or in ethical review and Christian doctrine. Furthermore, any analysis we make of LRECs must make similar imaginative journeys. Other sites frame the research question: how is it that informed consent means what it means in the context of LRECs? This question has an unspoken second clause: when it means something else to Bioethicists/lawyers/newspapers and so on.

Though consequential, these other spaces of consent are never fully present in LREC review. We hear of them or have them in our mind's eye. From this, though, it would be a mistake to think that we understand what informed consent means in these sites or the logics upon which it operates there. The descriptions LREC members give of the people who make up their local patient population, for example, can often seem stereotypical. We might feel that LRECs' emphasis on guidelines and standards colours a member's conviction that most researchers do not understand what is required for an informed consent from a patient. We cannot hope to extrapolate the meaning of these other sites, these other social worlds, from hearsay encountered in a study LRECs.

Informed consent clearly both persists and is altered depending on the context, and it is this that has, in part, enabled it to operate so successfully. Informed consent, then, behaves as what Star and Griesemer (1989: 393) describe as a boundary object:

> Boundary objects both inhabit several intersecting worlds… *and* satisfy the informational requirements of each of them. Boundary objects are objects which are both plastic enough to adapt to the local needs and constraints of the several parties employing them, yet robust enough to maintain a common identity across sites….. They have different meanings in different social worlds but their structure is common enough to more than one world to make them recognizable, a means of translation.

Thinking of informed consent as a boundary object provides a framework for understanding the decisions that LREC make. Within the site of LRECs, for example, informed consent has a particular meaning but it is also implicated in wider regulatory agendas. The harmonisation of global pharmaceutical regulation rests on informed consent. In sites other than LRECs, such as law courts, informed consent conforms to the different logic and agendas of those social worlds. Despite being an elastic concept informed consent is stable enough to enable the worlds of medicine, law, government, and even the public(s) to act collectively and make medical research happen

This analytical framework refocuses debate about informed consent. A common complaint by Bioethicists is that the informed consent in a legal setting law fails to do justice to Bioethical informed consent (Berg et al., 2001, Brazier, 1992). Moreover, much empirical work has concentrated on measuring informed consent exchanges between health professions and patients against what Bioethicists understand consent to be (Review, 2003, Sugarman et al., 1999). From the perspective of Bioethics, we should be analysing whether and why LRECs fail to understand or implement informed consent. Thinking about informed consent as a boundary object enables us to examine LRECs without understanding their behaviour as a failure. When LRECs insist that participant information sheets must be written on headed notepaper, with a contact telephone

number, a version number, and so on, it is not that they fail to understand informed consent as a mechanism for respecting patient autonomy. Rather, LRECs are operating according to a somewhat different regulatory logic where accountability and consistency (both of LRECs themselves and the researchers they regulate) are paramount. The question we should be asking about informed consent concerns success, not failure. How has it become so ubiquitous, the default principle in Bioethics?

We can see the success of informed consent in the way that many ethical problems arising in research are rendered as ones of informed consent when arguably they are much more complicated. This is true both within and beyond research ethics committees. The Nuremberg Code is often taken to be the beginning point in histories of modern informed consent. The abuses committed in concentration camps in the name of medical science, though, went far beyond not getting an informed consent. In a similar example, medical research was carried in the middle of the last century in the American South. Black men with syphilis were not told they had the disease and were not treated in order for researchers to observe the natural history of the disease. These experiments continued long after penicillin was found to be an effective treatment (Jones, 1992). It is obviously an outrageous abuse not telling these men they were part of an experiment based on withholding treatment from them. However, if these men had been told and willingly agreed to take part, the research would still have been morally problematic. Much more is at stake in these abuses of power than the failure to secure the informed consent of individual research subjects.

But because of its success in colonising bioethics informed consent has come to have intrinsic value. Bioethical problems are rendered as pertaining to informed consent when they might otherwise have been described in other terms. This is the effect that Ian Hacking (1999) describes as the social construction of kinds. No wonder that LRECs concentrate on participant information sheets and consent forms when it is informed consent that has come to have intrinsic worth beyond the boundaries of LREC meetings.

The imagined patient: paternalist informed consent

I want to end this chapter on informed consent with some discussion of effect of LREC decision making on informed consent, focusing on the distance between LRECs and the point at which consent is given. In the last chapter I described how informed consent serves as a process for transforming ethical subjects into scientific objects. In this transformation the site where a patient consents to research figures only indirectly in LREC deliberation. As a result informed consent for LRECs is essentially paternalist. As patients are only imagined, they cannot 'speak' and say what they need to know about research. Therefore committees must decide what is best for them, how educated they are, how much they want to know, indeed, if they want a choice at all.

The bioethical principle of this 'informed consent' from participants serves, as Foster (2001) describes, both a negative and a positive protection. It protects individuals from being enrolled in trials that they wouldn't agree to take part in if asked. Moreover, whatever the response to such an elicitation the very process of asking each person to decide for him or herself serves an intrinsic good. It is a recognition of the fundamental right of people to make decisions about their own lives. By seeking an informed consent from patients, researchers:

> give them an opportunity to exercise what makes them essentially human, pure reason, which is precisely, not weak. It is asking in our context, the clinician to respect that which is finest and most noble in human nature (Foster, 2001: 55)

When discussed in the abstract, then, 'informed consent' promises a mechanism by which a more equitable relationship between doctors and patients can be brought into existence. In the process of obtaining an informed consent from their patients, doctors perform a necessary step in respecting each patient's rights and responsibilities. Moreover, the consent process provides patients with the relevant information and in so doing so, supposedly, rectifies a power-knowledge imbalance between doctors and patients.

Within LREC review, however, informed consent does not necessarily serve as a mechanism for rebalancing power. For LREC members ensuring informed consent does not conflict with more paternalistic understandings of their role. LREC members see their review as about protecting patients. Within LREC review, a flawed or biased information sheet is yet another thing patients need to be protected from. For example, one committee member I interviewed said he thought the purpose of the review was to protect both the patient and the researchers. I asked him, 'protect them from what?' He replied:

> Patients should have adequate information to make an informed decision, and I think some people, some members of committee, are protective of their patients, in a paternal sort of way I suppose. I wouldn't be particularly strong on that. As long as they have read the information and understand what they have read they can make an informed choice C27

In LREC review, as this committee member expresses, informed consent is not the antidote to overly paternalistic medicine. On the contrary it is a bureaucratic extension of it.

For LRECs, ensuring that patients are able to give their informed consent is not about applying the principle of promoting autonomy. Indeed, the exchange at which patients give, or withhold, their consent is rarely considered by committees. As an anticipatory review, LRECs focus on the documentation before them. There is no mechanism for follow-up to see if researchers do as they say in the consent documents. Asked in interviews about the role of these documents in the discussion about consent, members are often unsure and emphasize the difference different research contexts would make. For example, I asked one professional member how she thought information sheets would be used in the exchange between professionals and patients. She answered:

> Good question. No I don't really [have an idea]. I assume that they all get the information sheet to read and I assume that most of them read most of it. But no I don't know. It depends what the nature of the study is. If it is you

> have just had a baby and I want to ask you some questions about the nature of the labour ward, lots of women would be quite happy to do it and wouldn't take much notice of [the participant information sheet]. But if it is 'you have got cancer and there is treatment option a or b and we are doing a study', then some people will read it much more carefully. And others will take the 'well you decide for me doc. If I was you daughter what would you do' approach. C45

This woman, a researcher herself, with experience of 'consenting' patients, reveals the true distance between ethical review and the point at which consent is actually given. The wider bureaucratic commitments to standardisation, administrative efficiency, and objectivity preclude any scrutiny of those other highly variable and locally contingent spaces and performances of informed consent.

In a limited sense, merely asking patients formally whether they choose to take part in research is promoting their autonomy, particularly if we compare this to cases where patients are enrolled in research without ever knowing about it. However, we should be clear that the existence of participant information sheets and consent forms (even signed consent forms) does not guarantee a patient has been asked to take part. Moreover, the exercise of each person's autonomy is surely individualised. In this each of us is not a generic patient, not even a generic incapacitated patient, breast cancer sufferer, or whatever. Each person is an individual, an Enlightenment Cogito, a Christian soul, a psychoanalytic Ego, or whatever quality we take it to be that makes each human animal unique and of intrinsic worth. This notion of being a generic kind of person, known transparently by another, is simply incompatible with the long tradition of thought through which the notion of autonomy has developed.

Conclusion

An informed consent from research subjects is central to contemporary framings of ethical medical research. As the Academic Bioethicists say, all things being equal, it is the right thing to do to ask people whether they want to

take part in research or not (Beauchamp and Childress, 2001). The disembodied and aspatial explanations that academic Bioethicists give of informed consent, though, need to be fleshed out. When we do, we see that informed consent is central to ethical review not because of the importance of respecting people's autonomy. Rather informed consent serves as a regulatory standard.

Bioethical problems are 'woolly'; they are local, contingent, and always contestable. In the face of a need to regulate - and be seen to regulate - such sites, a system has developed that forefronts what can be standardised, the participant information sheet and consent form. This paperwork, as immutable mobiles, is able to circulate between the spaces of informed consent, making collective action possible. It is the paperwork that is left ready to be called to account if it ever need be – promissory accountability.

Chapter 7

What makes LRECs local? And does it matter?

Introduction

LRECs are called 'local' Research Ethics Committees but are they local in anything more than name? There are many ways in which a committee might be local. It might think of itself as local (a local identity). This identity might affect the committee's review through an ability to speak for a local population (a local mandate) or through particular aims of the committee (a local agenda). The committee might have information or knowledge that has not been, or could not be, codified (local or 'situated' knowledge). The Oxford English dictionary defines 'local' as having the attribute of place or spatial position, belonging to a place, or having restrictive force. LRECs are certainly 'local' in some obvious senses. LRECs are made up of people from a particular area, albeit a bureaucratically defined area, and they are 'hosted' by particular, geographically bounded, Health Authorities[12]. Is there anything other than this that makes these committees local though? Could LRECs, for example, be said to have a local identity or a local mandate?

In the past the idiosyncratic nature of LRECs and their review, it was argued, betrayed their inadequacy. The researchers who had to apply to each and every committee, with their different application forms and different decisions, regularly bemoaned the situation in the pages of the medical press (Harries et al., 1994, Meade, 1994, Redshaw et al., 1996). Ethical research, it was argued, was not a geographically differentiated matter. As a *British Medical Journal* article put it, if research is ethical in John O' Groats then it's ethical in Land's End

[12] Health Authorities will here after be referred to simply as health authorities.

(Meade, 1990). Researchers were undeniably annoyed by the sheer time and energy involved in applying to lots of different committees (and indeed probably by the fact that they had to apply to anyone for 'permission' at all). However, their attitude also reveals incredulity that the ethical issues raised by research could be different in different places. Where LRECs demanded different, and sometimes contradictory, changes to research protocols and participant information sheets they prompted confusion, disbelief, and anger from researchers. With the standardisation of LRECs and their review recently instituted, we might assume that committees have become less 'local', or at least less idiosyncratic. All LRECs now must follow the same set of standards and procedures in their reviews. Indeed, as I discussed in the last chapter, the application forms and consent sheets they review now also follow a nationally standard template. However, the standardised review still retains a mechanism for what it defines as 'locality issues'.

As I described in chapter three, since 1997 there have been major changes that have affected the 'local' nature of LRECs. It was in that year that the Department of Health introduced Multi-centre Research Ethics Committees (MRECs) to review research that was to take place across many areas. In the subsequent period, the period I was undertaking fieldwork, the UK had a two-tier system of Local and Multi-centre RECs. The system made a distinction between small and large research projects. For a small research project, one that was taking part in fewer than five 'sites' (i.e. area covered by an individual LREC), one LREC in each health authority where the research was going to take place was charged with giving it what I call here a 'full review'. Where the LREC in question came to a 'favourable opinion' (i.e. approved the research) the decision held for that health authority. Large research projects, those being carried out at more than five sites, were reviewed by MRECs. MREC approved research then had to be submitted to the relevant LRECs for a review of any 'locality issues', what I am calling a 'locality review'. As part of this locality review the Governance required LRECs to assess the suitability of the local researcher, the

appropriateness of the local research environment and facilities, and considerations of the local community (Department of Health, 2001a: 8.8)[13].

With the integration into British law of the EU directive (2004), the system has changed again. A 'favourable opinion' from an accredited committee –MREC or LREC – now holds for the whole country and all other committees are now legally bound by that decision. The research must still go to a local committee for a review of Governance-prescribed 'locality issues'. Aside from the stipulation about locality review the Governance requires LRECs to consider any ethical issues arising from the 'concerned community' (9.18). These might include the likely availability of products resulting from the research (9.18d) or the 'enhancement of local health care' (9.18c). The Governance also suggests LREC consider the need for provision of information in languages other than English (8.8).

Despite these huge changes since the introduction of MRECs, the principle remains the same. The arrangement for ethical review assumes a distinction can be made in types of ethical issues, some of which can best, or perhaps even only, be reviewed locally.

The question of what local means to ethics committees is interesting not only because of these recent organisational changes. What it means to be 'local' has a number of somewhat contradictory connotations in the context of ethical review. A strong rhetoric of 'independence' runs through the LREC Governance (1.3). Here we might imagine local as potentially threatening that independence. Having colleagues review each other's research introduces personal biases and the danger of 'old-boy' networks becoming influential. In the interest of the kind of administrative objectivity I described in the last chapter the local aspects, in other words the non-standard aspects, of the review need to be kept to a minimum. There is a sense that if LRECs are 'too local' they are unaccountable to the researchers who apply to them or others who might be interested in their decisions. In the absence of binding external standards to invoke, researchers

[13] The Governance will hereafter be referred to simply as the Governance.

who are unhappy with a decision seem to have no way to challenge it because the criteria, procedures, and information used are not open and accessible to all. 'Local' then seems to introduce notions of both secrecy and even tyranny. Moreover, the idea that ethics reviews could be idiosyncratic prompts questions about their fairness. If researchers can carry out research in one place that others can't in another, isn't that unfair? If LRECs offer different levels of protection to patients in different areas of the country, aren't some patients being failed by the system?

Conversely, drawing on a different set of associations, a local review seems to promise a knowledgeable review, conducted by people in a position to assess the account of the research given on the forms. Committee members live and work in the area and are able to challenge researchers' characterisation of local facilities or needs. What is more, such a local review promises to be a more timely and convenient one. After all, if the committee has any questions for the researcher he or she is only down the corridor. A local review also promises the potential to allow local communities to shape the research agenda of their local area. Where local patient communities have suffered in the past from paternalistic or abusive doctors they may, through a local ethics committee review, help ensure this won't happen again.

In the light of the contested nature of 'locality', then, empirical investigation is needed to understand in what ways, and with what effects, LRECs are local.

A study of how these issue play out for LRECs has the potential to inform a number of empirically impoverished debates in Academic Bioethics. Bioethics assumes that ethics involves the top-down application of universal principles. Any allowable 'reflexive equilibrium' between moral intuitions and principles is essentially aspatial, occurring intellectually and not affected by embodied contexts. The notion that there are 'local' ethical considerations that can only be assessed in place poses interesting questions about such universal frameworks. Are 'locality issues' a mechanism for dealing with issues in ethics that just can't be made sense of in terms of universals? Issues that just cannot be resolved by

applying standards? If so, what types of issues are these and how do LRECs think they need to be dealt with? Are there spatial elements to ethics for LRECs and how might this inform bioethical theory?

One theoretical debate that an exploration of localness has the potential to inform is that of the importance of 'community' in Bioethics (Kuczewski and McCruden, 2001, Cecire et al., 2000). Communitarian writers, for example, stress the importance of community in formation and exercise of ethical positions. To a large extent, though, this 'community' remains vague, almost metaphoric. While such writers might argue theirs is a metaphysical rather than metaphorical 'community', if they are to contribute to understandings of actual ethical problems they must flesh out the relationship between ontological community and those things we, in our everyday life, call communities. It may be that an analysis of the 'localness' of LRECs can begin to colour the metaphors operational in communitarianism.

In this chapter I reflect upon what way LRECs are local. I begin by asking whether there are locality issues that need to be addressed as part of an ethics committee review. LRECs execute their locality review very differently from their consideration of the same issues in their full review. In the former, when they are asked to address locality issues explicitly LRECs seem at a loss as what to review. This prompted me to ask the committee members I interviewed whether they thought there are locality issues to be considered in LREC review. The different answers members gave reveal underlying differences of opinion about the nature of both ethics and ethical committee review. Given these differences of opinion, I turn to consider the locality review more directly. Although I had sat on an LREC for a long time before I began observing other meetings, I had no experience of these locality reviews. Because of the very specialised nature of the hospital whose LREC I sat on, no multi-centre research was conducted in there. I was surprised when I began fieldwork to discover how ambivalent LRECs often were about the review of these MREC-approved research projects and about how little they were able to say. Addressing each of the Governance's three locality issues in turn, I consider why it is LRECs are able to review locality issues in their full, but not their locality, review. I argue

that, in particular, the professional nature of the spaces of LRECs prevents a standardisation and separation of locality issue.

Are there 'locality issues'?

In my observations of other LRECs' committee meetings I was struck by how little LRECs had to say in their locality review. As I argue below, LRECs make important assessments when they undertake their full review of research. In the light of this I was keen to explore whether members thought there are 'locality issues' in an ethical review of medical research.

The number of different ways in which LRECs organise their locality review begins to reveal the uncertainty that they feel about it. In the meetings I observed some committees reviewed these applications as they did full applications, approving them on locality issues but sometimes writing long letter of recommended amendments to the MREC, which had approved the application in the first place. Other committees had a sub-committee of between two and four members that met separately to review these applications. These sub-committees then either reported to the committee meeting or directly to the chair. Where a sub-committee reported to the committee meeting there were huge variations in the form this took. Some reports were detailed and included the decisions made and reasons for those decisions. Other reports were cursory. Some committees interrogated the sub-committee members about their recommendations, and others did not.

Whatever the organisation of the locality reviews, though, members express an overriding feeling of incredulity about conducting a review of 'locality issues'. When asked, all members could list the criteria the Governance gives for locality review. I then asked them to elaborate on what the list means in practice. They were unable to do so.

Certainly, there is a feeling among many members that there is no scope for a local review beyond the rubberstamping of MREC approved large research

applications. One paediatric consultant described it all as 'a waste of paper' (C40). Each member on his committee was sent the application form, the consent form, and the participant information sheet of each of these research projects. For him, receiving all of this paperwork and having to lug it all to the meeting seemed ridiculous when 'it has already been approved' (C40). Another member from a different committee, a retired GP, said:

> We are only supposed to comment from the local point of view. Where there is local researcher, are they up to it and do they have the facilities? I think that we are allowed to ask for changes to the participant information sheet but only for local reasons. C37

I asked what these might be, and he replied:

> I can't imagine. We are fairly stuck with what we can do. C37

An overwhelming number of interviewees echoed his view that there is little room to be critical in the 'locality review'. This finding that LRECs see their role in the locality review of MREC-approved research as little more than rubberstamping prompts serious questions for the Department of Health. If there are locality issues to be considered it seems likely these are being neglected in review as it is currently practiced. If, on the other hand, there genuinely are no relevant 'locality issues' then this stage of the process can be withdrawn. Either way, the status quo does not hold.

Given the feeling from LREC members that they are rubberstamping in their locality review, I asked the committee members I interviewed whether there are any locality issues that need to be considered in an ethical review of medical research. Most members felt that there are. I turn, first, though, to the claim that there are no locality issues because this argument helps to make sense of LRECs' practise of locality review.

There are no locality issues

A few LREC members I spoke to felt that there genuinely are no local ethical issues to be considered in the review of medical research. One woman I spoke to, the chair of a relatively small committee in the North West of England, talked me through the locality criteria given in the Governance and described the flaws she saw in each one. It is worth describing her comments at length.

The first requirement of a locality review, an assessment of the suitability of the local researcher, she described as 'empty' (3). For although LRECs are told they must judge whether a local researcher is a suitable one they are not told how they are to make this judgement. The committees are provided with a C.V. of the local researcher. However, with no guidance on what qualities were desirable in a researcher, the chair felt that it is not helpful simply to be provided with this document.

The response from this woman, a doctor working in the North West of England, needs to be assessed in the very particular context in which it occurs. In the North West of England a GP, Harold Shipman, was able to kill probably hundreds of his patients before anyone raised the alarm. The effects of this case on this woman's view of ethical review are probably best described in her own words:

> ...there is an assumption that local people will know the local researcher better, and will therefore be able to make a judgement about whether they are a fit person to undertake research. But I have reservations about that. And sometimes it is not very helpful to have people who know the local researcher well on the committee because they're going to be biased, and understandably so. If they know them well then they'll say: 'oh yes he's a good chap'. But coming from [the North West] we always use the example of Dr Shipman because we thought that he was fine as a GP. And if we couldn't make a decision about whether he is a suitable person to be a GP then we can't really decide who is going to be a suitable researcher.
>
> C3

In one sense we could argue that due to the atypical conditions we should discount her view. However, we might equally want to argue it is precisely such abuses that the ethical review ought be designed to prevent. If so, such dissenting voices need to be taken very seriously,

The chair's views crystallise a number of important points that ought to be raised about an assessment of a local researcher's suitability, the first of the three 'locality issues' in the Governance. As the application process requires a C.V. of the local researcher be provided, it is fair to assume LRECs are supposed to use this to inform their assessment. This requirement frames the assessment as a judgement about the researcher's scientific and professional competence rather than any more explicitly ethical criteria. As I have discussed now in several different contexts, LRECs are primarily professional spaces. In chapter four, for example, I discussed how LRECs make proxy decisions based on applicants 'performances' of expertise. We could class a C.V. as another 'performance of expertise'.

Furthermore, the chair's answer poses a question about the sense in which the researcher's suitability is a 'locality issue'. If the Department of Health is content that this assessment can be answered by recourse to a C.V. then there seems to be no reason why this document should be reviewed locally, rather than as part of the MREC review. Conversely, if the assessment does require an acquaintance with the researchers, or their work, requiring that such an assessment be made locally is no guarantee of such familiarity. A local review of research might make such an acquaintance more likely, but there is also the possibility that any particular review won't be local enough. In other related contexts, such as grant applications, letters of reference are the preferred currency.

Moreover, as Timmermans and Berg argue, standardisation depends on and triggers standardisation (2003: 50). In her call for explicit criteria the chair of the committee in the North West typifies one response to increased scrutiny. She says:

> ... [what] we are asked to look at is the suitability of the researcher. But we are not told what criteria make a local researcher suitable. C3

It is not that this woman, a doctor and a researcher herself, does not know how to make such judgements about another medical professional's competence. Medical professionals make these sorts of judgements all the time, based on publication records, team affiliations, professional reputations, and letters of reference. However, these are often quite 'soft' assessments based on tacit personal knowledge and whether things 'look right'. What this chair of an LREC seems to be expressing here then is a discomfort at having to come out and make an assessment on the record, particularly in the light of this researcher already having been judged a suitable one by the people organising the research project. If she is going to be forced to make such crude assessments, as the Governance requires, she wants formal criteria by which she is to do so. I will return to this point later in this chapter.

The second criterion in the locality review requires LRECs to review the appropriateness of the research environment and facilities. Many more members I talked to, particularly professional members, were vocal about the importance of these sorts of issues. The chair of the North West LRECs, though, thought that while these were important issues they were not best addressed by an ethics committee. She felt they were primarily issues of resource allocation and research strategy and should be addressed as part of wider research and development strategy within the NHS Trust. Her appeal, in fact, is that the boundary work LRECs undertake as gatekeepers in the research process, as discussed in chapter five, needs to be transferred to another more appropriate site.

The final criterion is whether the local population raise any particular ethical issues. Again, she felt very strongly there were no issues for LRECs to consider here either. She argued that researchers would approach individuals to participate in research and nothing could - or should - be assumed about those individuals because of where they were recruited (i.e. the ecological fallacy). She

gave the example of her local area which, she said, had a large population of Catholics. The chair explained that some on her committee felt that research involving issues such as abortion and contraception had to be handled with extra care because of the Catholic population. This though did not follow in her mind. She said that wherever research was being carried out it could include potential participants for whom abortion or contraception were ethically or religiously problematic. It is a LREC's job to make sure that such research was discussed sensitively with potential participants so that no one, wherever they were approached, was offended. This question about the scale at which ethics needs to be addressed is a key one to which I return. In the mean time it is enough to note that for some LREC members, place does not incur any ethical issues.

A lay member of another LREC articulated a very different understanding of a local review, but one that also rejected locality review. This retired nurse felt that ethics review entailed a local (and personal) responsibility. Her committee spent a lot of time on each (full) application, she said, and so having to rush through these MREC-approved ones without being able to comment was frustrating for her. She felt very passionately that it was wrong for LRECs to consider only some of the ethics of an application. Describing the issue she said:

> I feel quite adamant that if these things are wrong with an application, even if it is not our job, we should be able to list them, [the MREC will say] 'well that's not your job'. But, as I said to the chair, 'well what if they miss something', which sometimes they do. And she replied, 'Then that's their problem'. But to me it isn't their problem. It is the patient's problem. As a layperson I take a grievance against that. But you are shackled. C44

Hers is an impassioned reaction against rules that 'shackled' her from exercising full ethical responsibility. The same member described the importance of 'locality' to me with the analogy of parenthood. She explained that if other people's children do something wrong you wouldn't necessarily correct them but, if it were your own child you almost certainly would. Because of the 'closer relationship' between an LREC and local researchers this member thought a local review was more exacting.

These two LREC members have starkly different understandings of locality review. One is the carefully reasoned dismissal of locality issues by a professional who is being required to take responsibility for decisions she does not feel able to. She is being asked to say that a local researcher, site, or community pose no ethical problems. In her everyday professional life she makes these decisions but they are incremental and enmeshed in ongoing everyday practice. If she has worries about the suitability of a fellow professional to undertake work they are there are accepted ways of dealing with this, ranging from a quiet word to formal complaints procedures. Medical professionals cannot say other medical professionals are unsuitable without serious consequences. If she is required, in locality review, to make a one-time judgement she wants more explicit guidance on what constitutes unsuitability. (This further guidance will, of course, in its turn be insufficient too.) The other understanding, an impassioned denouncement of 'incomplete' review, reveals a similar discomfort at having to take responsibility for locality review. The lay member does not view ethical review as a medical professional, but in actual fact her notion of responsibility is very similar.

The locality review of MREC-approved research is, in effect, an attempt to standardise the 'local' aspects of full ethical review. LRECs' practice of rubberstamping the applications reveals the consequences of this attempted standardisation. These members' accounts provide insight into why that might be so.

There are locality issues

Asked whether there are locality issues, many members said that there are. As I discussed in chapter four, many members feel that interviewing a researcher is an important supplement to the paperwork they receive. Similarly, many members said there are often important local aspects to research applications that cannot be divined through reading the forms alone. In one interview, with a research-active member of a LREC in a large teaching hospital,

I asked how her committee assessed locality issues. The response she gave typifies a commonly expressed view:

> [We ask] Would that work here? Who would be doing it? Can they manage? I think that ethical issues are placebased, often with these things there is background to the application, which you wouldn't know unless you know the players, that is often ethically relevant. C45

She gave a couple of examples where she thought background information had informed her committee's review. However, the cases she gave were of full LREC review and not of locality review (of MREC approved research). In actual fact, the types of judgements she describes only take place in the full LREC review.

LRECs make judgements about locality issues all the time in their own 'full' reviews of research. These judgements, though, are not made separately but enmeshed within a network of connected concerns. For example, a committee may have concerns that someone is doing too much research or does not have the right expertise to conduct particular research. Such a concern prompts the committee to conduct a more thorough review in other areas. They are very unlikely to come out and say a researcher would not be suitable to carry out a piece of research. As I discussed in chapter five, LRECs are both deferent to other professionals and reluctant to make such judgements unless they are couched as ethical, rather than purely scientific, LRECs tend to demand greater levels of assurance in other areas of the application, which in practice are judged in the round. Moreover, LREC assessments are primarily an assessment by a professional's peer group. As such they rely on the implicit and profession-bounded modes of reasoning. The locality review demands explicit yes/no answers to questions such as 'is this person suitable?' LRECs assessments of such issues, though, are tentative, contingent, and holistic. It is very unlikely an LREC would ever have enough evidence to come out, on record, and make an assessment of professional incompetence.

Conducting a local review

In their review of research, LRECs inevitably use knowledge and opinions that they have by virtue of their acquaintance with the local area, NHS facilities, and the staff employed locally. These judgments are integrated in to the review as a whole. In their full review LRECs are not required to distinguish between issues that are local and those that are not. Committees are thus freed from making stark judgements about, say, a researcher's ability to conduct a piece of research. The discussions LRECs have, though, have strikingly similar elements to the ones defined in the governance as 'locality issues'. I discuss examples of each of the locality issues in turn.

The suitability of the local researcher

All LREC applications must be signed by a principal researcher who in doing so takes responsibility for that research project. Whether this researcher is in a position to take such responsibility is one of the issues that LRECs consider in their review. This assessment is based, although not exclusively, on how the researcher completes the application form, on the committee's view of applications the researcher has made in the past, and on what the committee knows about the researcher from other sources. To a considerable degree, then, the 'localness' of the review turns on the extent to which a committee's assessment of a researcher's suitability is informed by tacit local knowledge not contained in the submitted application form. That, in turn, raises the question of what such contributions add to the committee's review and whether it threatens the values of independence and accountability stressed by the Governance.

As discussed above, the purpose served by requiring a C.V. from the researcher is unclear. If a committee is already acquainted with a researcher, then a C.V. may not tell them much that they do not already know. If the committee do not know the researcher then, some committee members feel, that a C.V. does not provide enough information to a make a proper assessment, especially when the criteria for that assessment remain unclear. Certainly, where researchers are

prepared to lie, a LREC would offer little protection. Fraudulent researchers aside, the question of what sorts of discussions LRECs should have about local researchers' suitability and in virtue of what knowledge is an important one.

LRECs' concern with the suitability of the researcher depends on how confident they feel about the application as a whole. LRECs pay particular attention to the researcher's suitability in cases where they judge the potential risks of the research to be high or where the patient population is judged to be a particularly vulnerable one. Therefore, research involving particular drugs or research conducted on children or mentally incapacitated patients will invoke a more rigorous consideration of the researcher's ability to carry out the research well and safely. The introduction of an application (as described in chapter four) often includes some sort of comment about the researcher's standing, for example, that he or she is a leading expert in this field or that this application is just like a previous application made to the committee. This fore-fronting of an individual researcher (rather than a research team) re-emphasises the named researcher's responsibility for a project and reflects the hierarchical nature of medicine. It does not imply the committee knows the researcher. However, if someone on the committee does know the researcher he/she will usually make it known.

At times, though, LRECs clearly use 'local' or background knowledge in making an assessment. For example, in one committee meeting I observed, an application was considered involving research on delusional patients. The principal researcher was described as a gerontologist on the paperwork submitted to the committee. One member of the committee was concerned that the researcher would not have the proper experience and expertise to work with this group. Another member however confirmed this researcher had lots of clinical, although no research, experience with this vulnerable patient population, delusional patients. The committee's concerns were assuaged and the application, after due discussion, passed.

How well a researcher is known to a local committee is bound to vary hugely. Professional members of an LREC are likely to work in geographical

proximity to the researcher. However, this is no guarantee of reliable knowledge of researchers or their work. There will be cases where LRECs think their knowledge is reliable but others might not (be that the researcher him/herself or someone else – the dreaded lawyer of a wronged patient perhaps). However, I did witness many reviews where one member of the committee was seemingly able to comment authoritatively a person's competence.

On a few occasions I observed meetings where a committee member declared a conflict of interests. In a sense, this is an identification by a member that they are 'too local' to take part in the review. Researchers are not allowed to send their own research to a committee on which they sit. On one occasion I observed a committee meeting where a member was married to researcher seeking committee approval. The committee member raised the issue and said he and his wife had discussed it. For logistical reasons she had decided to submit the research to the local LREC but if the committee were not happy to review the project, she would submit it elsewhere. The chair said he was happy to conduct a review and invited the rest of the committee to make any objections. No one did. The member offered to leave the room for the review but the chair didn't think that it was necessary. In another, more typical, example one member of a committee had links with a particular research team although had not been involved in the particular research proposal under review. On this occasion the chair decided the member could take part in the discussion but not the decision-making. These 'too local' or immediate working (or personal) relationships, though, were rarely evident in the committee meetings I observed. To what extent biases introduced by such relationships would be amenable to the observations of someone like myself is debatable. However, there did not in the course of this research seem to be any such biases in LREC review.

It was very rare that discussion of the researcher's suitability included any explicit moral assessment of them. Very occasionally, though, I witnessed one member defend a researcher in that way. One example occurred in a LREC meeting where they were reviewing a proposal that involved testing ultra-sound equipment using aborted foetuses. One lay member of the committee said he found the research abhorrent. The committee discussed the research, trying to

assess what exactly the research would involve and at what point the women's consent would be sought. Their discussion turned on how normal this type of research was and whether the researcher had done anything like this before, both of which it was impossible to judge from the application form that had been submitted. The same lay member re-iterated his feeling that he was still unhappy with the nature of the research, and that the committee should not pass it. Most of the committee obviously felt there was more to this application than was written on the form and wanted to find out more, whereas this one member just wanted to reject it outright. After a bit of to-ing and fro-ing, with members becoming more entrenched in their positions, the chair closed the discussion by saying that he thought the researcher was an experienced scientist and a compassionate man and therefore there must be something that had not been explained properly. His decision was to refer this application back to the researcher for clarification. Statement about a researcher's compassion, are, however, unusual.

On the whole committee deliberations about whether a person is a suitable researcher or not turned on technical and scientific questions rather than explicitly moral ones. As described in chapter five, the science and ethics are emeshed and co-existent in LREC deliberation. It could, of course, be argued that it is unethical to let a person without the right qualifications or expertise hold a position where they might be able to harm research participants. However, the principle investigator is not necessarily the person who will come into contact with patient. This is particularly the case on bigger projects. Moreover, as this question is rendered in the Governance as one involving a judgement about expertise we might ask whether research ethics committees are the best people to make this assessment. As the committee will often not have expertise in all areas of research, they frequently make such decisions on the basis of the performance of expertise or symbolic markers of it such as publications, and funding.

That this is a professional/technical decision-making process mitigates, in the minds of LREC members, personal biases that might otherwise be felt in reviewing a colleague's work. This understanding is not confined to professional members of committees. The lay chair (C38) of one committee told me he depended on members of his committee knowing the local researcher in order to

decide whether he or she was competent to carry out the research. He gave two reasons for his confidence that no conflict of interests or 'old boy networks' would operate. He said LREC members are never reticent about criticising other researchers or their work. He put this down to the 'scientific attitude' that makes it normal to criticise other research, what Merton (1942/1973) famously called 'organised scepticism'. In fact, this lay member thought professional LRECs members review their co-workers researcher more thoroughly. This critical attitude was fostered, he thought, because the meetings were closed and confidential. The trust created among committee members enabled them to speak freely about their true judgements.

Other members expressed similar views. One important way in which committees know particular researchers is through the past applications that they have made to the committee. In one meeting a committee decided it wanted a researcher to resubmit an application. When I later asked a professional member of the committee why they had reached that decision she explained:

> [Because the principal researcher usually] submitted first class applications and this one wasn't. It was second-class. It may have been that had someone else submitted it we would have been less harsh. You don't want to make an example of anyone but all the same you don't want a good researcher to let their standards slip. C18

What is interesting about this response is that it confirms the earlier committee members' assessment of knowledgeable close links between research and committee being more exacting. Despite concerns about the potential for bias when members and researchers know each other, generally LREC members generally think that 'knowing the researcher' is a good thing when it comes to ethical review.

One of the things that emerges from talking to LREC members about the nature of being a local committee is that the professional inter-dependence of researchers and committees is a taken for granted part of ethical review. As the chair of a teaching hospital explained to me:

> Some departments are over represented (in terms of the applications made). Rheumatology applications are most numerous. So although there are no specifications or requirements of members (for this area) on the committee, it can be useful to have people from the departments as they have special insight. We used to have a rheumatologist, which was useful, but we do not have him now. It is useful to have people who can give backgrounds to the studies and who have done particular projects. C14

I asked him how the committee now deal with these applications. He said:

> Things get referred back for clarification, which may slow things down a little. [The committee seeks clarification on] things like standard practice. We keep writing to the rheumatology department asking for a member, but no one has said yes. C14

In this conceptualisation LRECs operate as a common good without which medical research would not be able to take place. Having members who know each other is a function not just of having the expertise needed on the committee, but of the collective responsibility for undertaking ethics review. If this burden is shouldered at a 'local' level, departments that are particularly research active are likely to be required to carry a proportionate responsibility. This dynamic ought to lead to local committees weighted toward the research specialism of that area. (Meaning also LRECs are more likely to know researchers more directly).

Committees often have knowledge of the researcher beyond what is written on the application paperwork. This is sometimes quite straightforward information that the researcher failed to supply. Alternatively, it is sometimes much more in-depth or value laden knowledge that results from local affiliations or professional experience. Where committees have no such knowledge they make assessments based on the information they have provided, such as assessments about a researcher's expertise and the amount of other research they are currently undertaking. (There is of course a balance to be had between the two as being involved in research is a marker of expertise but having too many

projects on the go at once is thought to threaten the standard the research will be carried out.)

Depending on your position, some of these local knowledges and informed ways of working are more desirable than others. A qualitative researcher, for example, may reasonably prefer a review by other qualitative researchers rather than a geographically local one. What is clear, though, is that the assessments committees make about 'local researchers' predominantly concern scientific rather than ethical competence. In these assessments there exists a necessary tension between knowledge and independence. This tension reflects the need to make right decisions and being seen to make right decisions. It also involves wider issues related to the judgement of scientific knowledge.

The appropriateness of the local research environment and facilities

Local assessment of a research environment is a potentially less problematic evaluation than that of a professional's suitability. The questions and sources of evidence required to carruy out this evaluation are more straightforward, and not so reliant on assessments of expertise, although these are issues are indirectly present. However, the researcher submitting the application has made his or her own assessment of suitability. If a committee then decides local facilities are not suitable, it is indirectly challenging the researcher's professional judgment. The committee's assessment of local research environment, though, operates in a similar way to that of the assessment of the local researcher. It is an issue that it much more likely to be raised when a committee has other concerns about the research.

In research where, for example, the researcher is a student, the patients are vulnerable, or there are big deviations from standard practice, LRECs are more likely to ask more probing questions about the research environment. For example, I observed the review of a piece of student research investigating recovery after a certain operation. The research involved patients taking various exercise tests. The committee discussed the application and was concerned about whether the facilities would be adequate if something went wrong, if for example

a research participant had a heart attack. Their concern stemmed from the fact that the investigator was a student and thus not experienced. The committee required confirmation that the place where these exercise tests were being done had experienced doctors and equipment that could be accessed if someone became ill during the exercise tests.

In their full review of local research, committee members feel reasonably confident in their appraisal of the suitability of facilities. On the whole, members I spoke to were enthusiastic about the importance of this area of their review. This response by a lay member of a committee is typical:

> Yes. There is [something gained]. We all live and work in this area. We pretty much know the area and we have had a couple of people say, for example, 'oh no that sites not appropriate. It's not wheelchair friendly and they are dealing with disabled people'. And that kind of stuff is really valuable. C36

I return to an alternative view, as typified by a chair who argued there were no locality issues, below. However, it is worth noting that this lay member identifies living in an area as providing knowledge of local health research facilities. In the observations of LREC meetings I made, knowledge of the local facilities was a professional assessment. In general, it was professionals who worked in the area rather than lay members who had used the facilities as patients, who provided it.

It was clear from my observations of meetings that committees were often able to bring important knowledge about research facilities to bear on their decisions. In one extreme example the unsuitability of the local research environment meant the committee rejected the application. The research was submitted not by a medical professional but a sociologist. It was a piece of qualitative research aimed at assessing the impact of reorganising and redecorating a ward. The research asked whether a different physical environment would create better working conditions for the staff and a better therapeutic environment for the patients. Although one committee member thought the research was 'bad science', the predominant issue the committee

discussed was the suitability of the ward proposed for the research. On the face of it there were no obviously insurmountable ethical concerns. The patients were a vulnerable patient population group but the research took care to take this into account. The LREC had serious concerns about the burden the research would put on to an overstretched ward. The ward had staffing problems: 18 out of the 20 nurses were agency staff. The chair of the committee had contacted the ward manager to seek advice. She was reported to have expressed ambivalence about the research that the committee read as opposition. Under these conditions the LREC felt the research would be disruptive and damaging to an already problem ward and that the research results would be less robust because of this atypical case study. The committee therefore decided to reject the proposal. In this instance knowledge of the local condition affecting a 'research facility' proved hugely influential to the decision reached by the committee.

Inevitably a committee's knowledge of local conditions and research facilities will always be partial. An active researcher on a committee explained that, as she did not work in the host hospital, she did not usually have much to say about these sorts of issues. However, other members of her committee might object to research that threatened to over research certain patient populations or went against local policy. One centre within the local hospital was doing a great deal of research, and as a result there was always the potential that patients would be either subjected to too many requests to take part in research or to too many research projects. The member explained:

> I do not usually have much to say on that [these local issues]. But somebody at the [centre within a hospital], where patients are being recruited routinely into studies, could say this is yet another study. Patients coming in to have knee or hip replacement are popular for studies, and [person] could say this group is over-researched, and could someone go back and check with local managers that that is ok. C16

This same member highlighted a different example of similar issues:

[Another person] who works at the [hospital], made comments on the ethics of research, where a lot of the patients are using the maternity services are from an ethnic minority. The Trust has policies on ethnicity and inclusiveness and diversity, so we cannot have research going on which goes against that policy. So that is the sort of thing we get from having people from local institutions. But we do not have people from all of them, so I do not know if we have good enough coverage. I am interested in what those people have to say about the impact of research on the institution.

C16

LRECs usually review research from more than one institution. As this member suggests, it would seem that committee's knowledge is contingent on who happens to be a member of the committee.

Where members do rely on this background knowledge, the tension between being informed and biased is greater than ever. The first quotation in the paragraph above in which the member discusses over-researching a patient population, for example, exhibits that tension between local knowledge and independence. It could be that the committee member who says 'this is yet another study' is actually protecting this research 'patch'.

Before moving on it is important to reflect on the point raised by the chair of the committee in the North West expressing the view that there are no locality issues (discussed above). Her argument turned on two issues: first that these aren't ethical issues per se and second that they ought to be addressed by people with responsibility for research and development strategy. Regarding the first of these points, an argument can be made either way. It could be argued that to conduct research involving participants who use wheelchairs in a building with no wheelchair access is unethical because it is an abuse of the dignity of the people. Equally, one could argue that to do so is stupid and needless but not fundamentally unethical. Perhaps the better way of assessing the issue is not whether these issues are ethical per se but asking whether ethics committees are well placed to make these assessments. Answering this second question involves making an assessment of a counter-factual. I am not attempting to do that here.

However, I do though think this is an important question that ought to be considered by the relevant policy makers.

Consideration of the local community

The third and final of the locality criteria set out by the Governance requires LRECs to take in to account any ethical issues that might arise because of the nature of the local community. The question of what LRECs think considerations of the local community entail is particularly interesting because it turns on how they interpret 'community' and 'place' with regards to ethics. This criticism has the potential to extend the review beyond purely professional or technical assessments. In the next chapter I return to the related question of whether lay members are able contribute to ethical review in virtue of representing the local community. For the time being I describe the range of evaluations LRECs make that could be classed as considerations of the local community. I have categorised these as broadly involving local health issues, local scandals, and local language. Before discussing each in turn I want to draw out what is written in the Governance about this criterion.

For the most part the Governance articulates an aspatial notion of community. There are also some fleeting hints at spatially bounded community. LRECs are charged with 'protect[ing] the dignity, rights, safety, and well being of all actual or potential research participants' (2.2). These actual or potential research participants are implicitly located relative to research sites. Community has a more direct spatial positioning in one of the five 'community considerations' given (9.18). LRECs are asked to reflect upon the extent to which the research 'contributes to capacity building, such as the enhancement of local healthcare' (9.18.c). However, despite classifying community as a 'locality issue', the Governance actually outlines a primarily aspatial notion. In its use of the term the document posits a community of people suffering from the same illness. LRECs are asked to consider how the results of research will be disseminated to the relevant communities (9.18e) and whether the communities will be able to access the products of successful studies (9.18d).

Certainly communities can be either spatially bounded or not. However, the confusion between these different types of community and their classification as a 'locality issue' suggests a lack of conceptual clarity and thus the possibility of problems for the successful implementation for the Governance. A key issue that must be addressed in talking about communities is who gets to speak for a community and through what processes. Certainly communities do not spring into being because a government document requires it. If a collection of individuals do not self-identify as a community, these issues become even more problematic. In the next chapter I turn to the role of lay members on the committee. One possible understanding of their role is as representatives of the local community. I argue that if it is this, rather than any of the other possible roles I describe, that lay members are to play in LREC review then attention needs to be paid to the mechanisms for choosing the members who 'speak for' the local community. Without such attention these members lack legitimacy.

In contrast to the predominant conceptualisation of their Governance, it is a spatially conceived 'what it is like here' that makes up LREC notions of community.

> Well, all of us on the committee live and work here so we know the local community. We....know what they want from their local hospital. C10

There are three broad ways in which LRECs thought this spatially bounded idea of community was ethically significant. The first concerned the health needs of the local population and its impact on the ethics of research. Despite not being raised very often, when it was raised, it was taken very seriously by committees. Health is place-based with certain areas exhibiting much higher instances of certain illness and disease than others. The important causal mechanism in the relationship between health and place is poverty (Shaw et al., 1999). The geographies of health and inequality affect medical research, both in terms of availability of potential participants and how much the local population would benefit from medical advances in the treatment of certain diseases. I spoke to one lay member who sat on an LREC in a de-industrialised city with a reputation for

social deprivation. She said because the local population had particular health needs it was the committee's responsibility to encourage research into the health problems that local people were more likely to suffer:

> There is lots of heart disease round here. This is a depressed area. We have a lot of research on the diseases of poverty, you know, smoking, drink, heart attacks. We encourage it. The people here have a lot to gain from this (research) projects C23

Similar sorts of assessments were made on a number of LRECs which served areas with large ethnic minority populations. Certain illnesses are related to ethnicity and therefore certain areas promise more fruitful conditions than others for particular sorts of research.

These considerations of a local community's health needs are necessarily mediated through the structure of the local health services. Large hospitals and especially teaching hospitals deal with a lot of referrals, for example, and therefore the demographic make up of the local community is less likely to indicate the demography of their patients. Moreover, this notion of interplay between local community and ethics is primarily a professional assessment based on experience of working within the local NHS.

A second manifestation of 'consideration of the local community' involves committees assessing medical research in terms of local sensitivity caused by scandals. These might be very localised scandals or ones that have reached the national press but occurred locally. As with the professional member of the committee in the North West whose views about ethics were informed by the issues arising from the Harold Shipman case, scandals change the way committees view ethical review. In one typical example, a LREC I observed rejected a piece of research on smear tests. In the past year a local hospital had misdiagnosed a batch of cervical smear tests and sent out the wrong results. The LREC rejected a piece of research which involved additional tests being carried out on the tissue removed during smears. It was not that the research was

unethical in itself but the committee viewed the whole subject as too sensitive in that time and place. A member of this committee told me that both staff and patients had already been through too much to expose them to the additional stress of taking part in this research project. Again, these issues are not raised often but where they are the committee takes them seriously.

Finally, by far the most common way in which committees consider the local community is in terms of the particular language needs of a local population. At the time of the research, a number of public services were being reassessed in an attempt to eradicate institutionalised racism. In the years immediate prior to the time I undertook fieldwork, the Stephen Lawrence Inquiry reported (February 1999) and charged the police force with 'institutional racism'. A similar inquiry was considering the treatment of black and ethnic minority patients by the mental health services. When it reported in December 2003 it found these services to be institutional racist (Blofeld, December 2003). Furthermore, the Race Relations Amendment Act passed in 2000 in the wake of the Stephen Lawrence Inquiry made it a statutory duty to promote social equality. Within ethical review, with its emphasis on participant information sheets, this duty to promote social equality has become equated with a duty to insure the translation of information sheets. In highlighting this reduction (of social equality to translation I do not mean to suggest that translation of participant information sheet is not a good thing nor that people who do not speak English should be excluded from research. I do, though, believe there is the need properly to assess the ethical issues arising from research as it relates to race.

Whilst all the committees I observed showed a similar concern for the issue of translation of information sheets, they had a number of different attitudes to the problem. A number of committees accepted time and cost sometimes make it impractical to translate participant information sheets in much small scale or un-funded research. Where this was the case, committees generally required researchers to include not speaking English in the exclusion criteria of their protocol. Other committees were less prepared to accept the cost of translation and interpreters as a reason for excluding people from research. On some

committees they were happy to let family members translate for patients, whereas in others they required a professional translator.

On some occasions, I observed LRECs make a clear reduction of the racism to linguistics. I witnessed some heated debates about the rights and wrongs of excluding non-English speakers. I saw an entirely white committee challenge a black researcher about the ethics of excluding ethnic minorities through not translating information for participants. The implication by the committee that the researcher was being racist was met with disbelief as the researcher pointed out that lots of black people can speak English. Ninety-one percent of those who responded to my questionnaire were white[14]. This is arguably key in explaining why committees haven't been more critical of the equation of race with language.

In all three of the Governance's locality criteria LRECs, in their full review of medical research, make many valuable contributions based on their 'local', situated knowledge. This is not the case in their locality review of MREC approved applications. There will always be a tension between these local knowledges and an independent standardised review. Members themselves believe their professionalism adequately addresses the tension. Whether those external to the review, researchers themselves, policy makers, wronged patients' lawyers, the lay public, think this is the case is, of course, a separate matter. But a review that attempts to do away with local knowledge is an impoverished review. As the attempted standardation of locality issues, in the locality review of MREC approved research show we risk reducing review to a rubberstamping exercise.

Conclusion

It is no surprise, given the stress that has been put on the importance of standardisation, that the localness of committees is a complicated matter. Being a

[14] Survey data

local committee has the potential to disrupt the uniformity, predictability, and even the fairness of the decisions a committee makes. Members express different understandings both of the extent to which LRECs should be thought of as local and its value. Some members see proximity as resulting in more exacting ethical decision-making while others see it as a better-informed review. Still others expressed the view that there are no real local ethical issues.

This research reveals fundamental issues that need to be addressed about the way locality issues are reviewed by LRECs for research that has already been reviewed by MRECs. The criteria that have been given for these locality reviews are very broad. Nevertheless, they do though accurately represent the types of issues raised by LRECs during the performance of full review. However, the criteria are rendered useless, as they do not take proper account of LRECs as professional spaces. Their reasoning involves an integrated assessment of research projects. LRECs do not consider one issue and then move on to the next but make their assessments about the whole. For example, in research projects where they are concerned because the researcher is undertaking a new type of research, they will review the protocol more thoroughly. The way the MREC system is structured does not enable LRECs to perform a meaningful locality review.

What is clear from my research is that, on the whole, LREC members feel there is much less of a threat of personal biases impinging on their review. Committee members feel theirs is a professional review with adequate check against these problems. Researchers or aggrieved patients, of course, may well disagree.

While it is clear from the observation of meetings that there are ways in which it matters that ethical review is performed locally, this is primarily because in a local review it is likely that a committee can inform their review of the paperwork with personal knowledge and background information. This 'background' information is sometimes gained through working in the same area. It is equally likely to be gained through knowing who to contact about research or through applications the member of research teams have made in the past.

There are indeed communitarian aspects to the review. As I described in the last chapter, informed consent operates paternalistically within LREC review. Community operates in a similar way. Certainly, 'communities' are present in LREC review, be they patient groups, in particular 'vulnerable' patient populations, or the communities with particular health needs, i.e. poor or ethnic communities. Certainly, the people in these communities are treated in LREC review as the autonomous individuals that academic Bioethics posits. These communities, though, are not self-defining or self-determining. Professionals name them and act on their behalf. What an empirical study of LRECs can teach communitarian Bioethicists then is that the appearance of 'community' in Bioethical reasoning need not be emancipatory. Its value needs to be assessed on a case by case basis. We need to ask of, communitarian bioethics, what community? And who gets to speak for it?

In the next chapter I address the role lay members can play on LRECs. As I discussed in this chapter, lay might serve as representatives of the local community. In light of the professional nature of LRECs and their deliberations, what contribution do lay members make? In the next chapter I turn explicitly to address this question.

Chapter 8

Are lay members on LRECs just wasting their time?

> ....what we want to do is consider how to make good decisions in the right way.
>
> (Collins and Evans, 2002: 236)

Introduction

Ordinary members of the public are, as never before, being invited to get involved in making decisions once the preserve of experts. Within the National Health Service (NHS) for example, public participation[15] has become a *prima facie* good beyond question (NHS Management Executive, 1992, Litva et al., 2002, Milewa et al., 2002, Davies, 1998). LRECs are no exception and committees must now have lay members sitting along side the experts. Like motherhood and apple pie, public participation has much to recommend it. Many questions now facing the NHS, such as whether Multiple Sclerosis drugs should be freely available, are not purely medico-scientific ones (Burke, 2002). Certainly, they will not be judged as such in the media or at the ballot box. To involve the public in decision-making ought to allow their experiences and opinions to be incorporated 'up stream' (Willis and Wilsdon, 2004). Moreover, members of the public, whether as litigants or as NHS customers, are increasingly said to have a right to influence how the NHS is run. However these rights are conceived, it seems only right and proper to acknowledge the political rights of the lay public and to let them have their say. It is hardly surprising, then, that the NHS, a publicly funded organisation, has sought to increase the legitimacy of its decision-making through measures of public participation In this

[15] I use the terms 'public participation' and 'lay participation' interchangeably.

context lay participation has become a mark of fair and sound decision-making in the NHS.

Beyond such vague aspirations, there are a variety of rationales for involving the lay public. That lay participation is lauded in areas as diverse as censorship (Farrow, 2001) and land-use planning (Davies, 2001) should serve as a warning that it means many things to many people. If participation is to be effective we must be clear what we expect lay people to contribute and how we expect them to do so. In answering these questions we must grapple with contested epistemic and socio-political claims about expertise. What, if anything, can non-experts contribute to technical decision-making? Do lay people have a political right to be involved? What becomes of such a right if a knowledge-gap prevents their active participation? At the heart of this debate has to be the recognition that a fair decision-making process and a good decision are not identical. Choosing to make a decision in the 'right way', say through public participation, may result in the right answer, based on sound scientific truth, being sidelined or ignored.

In the 1991 government guidance to LRECs, lay involvement on committees was suggested but not required (Department of Health, 1991), and as I discussed in chapter three, research found that lay membership was far from universal (Neuberger, 1992). The 2001 Governance both tightened the definition of 'lay' and increased the required number of lay members on a committee to a third of the membership (Department of Health, 2001a)[16]. The lay membership of LRECs must include people independent of the NHS (6.5), people who are not (and have never been) health or social care professionals (6.7), and people who are not (and never have been) involved in research on human participants, their tissue, or data (6.7). Additionally, the appointment of lay members must adhere to Nolan standards for public life. The Governance clearly aims to a create a very different lay constituency to that of the hospital chaplains and solicitors of the past (Neuberger, 1992).

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[16] The Governance refers to the 2001 Governance. For the rest of the chapter it will not be referenced.

Despite this increased attention to lay participation, the Governance is silent about the role these lay members should play on an LREC. LRECs are, as I described in chapter four, primarily professional spaces. It is important, then, to assess the extent to which lay members encounter difficulty contributing meaningfully to LRECs' discussions or decisions. Given the absence of a formally defined role for lay members on LRECs and competing theoretical conceptions of the value of lay participation in decision-making, I examine the rationalisations of lay membership given by those who undertake reviews and, based on my observations of LREC meetings, the contributions lay members are able to make in actual practice.

In this chapter I show the effect of tacit and unformulated commitments within this process of public participation in decision-making about healthcare. I explore whether there is a contribution lay people can make to the ethical review of medical research by virtue of their laity. I begin by examining the theoretical rationalisations for lay participation in expert decision-making. I outline debates concerning lay knowledge, with particular reference to the potential tension between the lay public making an epistemic contribution and the lay public having a political right to participate. I then highlight the often fuzzy distinction between lay people and experts on LRECs. Lay participation is a social process. Those involved are both self selecting and transformed by the process. It is important to problematise too simplistic a notion of laity. I describe the different conceptualisations LREC members give for lay involvement and assess how these play out in practice.

Rationalisations of Public Participation

The quotation I opened this chapter with makes a distinction between making good decisions and making them in the right way. Using this distinction I describe four possible rationalisations of lay participation. The first two models, of the experiential-expert and the non-certified-expert, posit that under given circumstances lay people have substantive knowledge to contribute. Alternatively, the later two models, of extra-scientific and scientifically-engaged

participation, posit that public participation is a justification in itself: it is the 'right' way to make these decisions.

Evidence of lay people contributing to techno-scientific debates challenges the traditional assertion that such questions best left to the experts. Examples such as lay people identifying and proving causal relationships between environmental hazards and ill health (e.g. Popay et al., 1998, Bloor, 2000, Wynne, 1996) show that lay people can contribute evidence that answers scientific questions. A strong argument for public participation could be made if we could show that such examples demonstrate the potential of lay involvement. But these cases are limited. Very rarely do the lay public contribute substantive knowledge that settles a scientific uncertainty. This is partly accounted for by the different 'languages' spoken by professionals and non-professionals: the different framing of problems, the use of technical terms, and so on. The difficulty in 'translation' between the lay means of expression and those of professionals (Collins and Evans, 2002) is exacerbated by experts' unwillingness to accept the competence of the lay interlocutor (Popay et al., 1998), which is potentially compound by sexism and racism within a predominantly white male decision-making élite (Williams and Popay, 2001). If a case for public participation is to be made on the back of past contributions we must identify when there is the possibility of lay people making such contributions and how 'translation' between expert and lay ways of speaking and understanding can be achieved.

There are two possible epistemic justifications for lay contributions, and two corresponding models of public participation.

The first I call the experiential-expert model of public participation. Whereas experts are more likely to make abstracted and universal truth claims, lay truth claims are more likely to be phenomenological and 'situated' (Haraway, 1991, Williams and Popay, 2001). These are gained through the daily course of living and 'derived from the particular – the particular locality, biography and body – (which) is increasingly recognised as very rich and directed at different ends to "objective" expert knowledge systems' (Williams & Popay, 2001, p. 31).

A model of public participation based on the model of the experiential expert would require deciding what experience is relevant and thus who could participate in public participation. It may be that experiential experts, such as residents affected by science-induced illness, present themselves for inclusion in decision-making processes. This model of public participation would require setting criteria for who is to count as an experiential expert. Criteria for assessing participants' contribution would also have to be set. This model potentially legitimates vast public involvement.

The second epistemic model I call the non-certified-expert model of public participation. Based on the arguments of Collins and Evans (2002) it justifies restricted participation. They argue that non-experts have been able to contribute to technical decision making, not by virtue of being non-experts, but by having non-certified expertise. It follows not that we should allow all non-experts to participate in decision making but that we should re-examine the grounds of designating expertise. Rather than equating professional training and certification with expertise we need to formulate a normative theory of expertise which extends to others (such as Wynne's (1996) sheep farmers). They argue that without a normative theory of expertise we are on a slippery slope to relativism in which political rights are confused with what is epistemologically right, participation in technical decision making becomes universal, and there are no grounds for distinguishing opinion from technically sound knowledge (Collins and Evans, 2002). They state that whilst there are some questions that ought to be settled by recourse to wider public consultation, issues of scientific uncertainty are properly the domain of scientific experts (Collins and Evans, 2002, Prior, 2003). I concur with Collins and Evans in their insistence on the need for a rigorous justification of which debates the public should participate in. However, their own justification is either incomplete or circular. For members of the public to be able to participate they must have non-certified expertise. However, it is not clear from this account on what grounds, apart from successfully participating one gets designated as a non-certified expert. Furthermore, their desire to disentangle political rights and expertise (that is power and knowledge) is not only theoretically problematic, it is practically impossible (Jasanoff, 2003).

Alternatively, public participation can be conceived as primarily concerning values. From this perspective, scientific questions are ineliminably social questions and public participation provides a check on science being taken inappropriately from the laboratory to the real world beyond. Lay people can challenge the technocratic rendering of problems with the social and moral filters through which they live them (Adam and Van Loon, 2000). We can understand this as a 'soft' claim: science is objective and the domain of experts, but for scientific solutions to be effective social context needs to be considered. As Sullivan, talking about the relationship between doctors and their patients, says: 'Facts known only by physicians need to be supplemented by values known only by patients.' (Sullivan, 2003, p.1595). From this follows a model of public participation which values the public for their ability to make social assessments of science. I call this extra-scientific public participation. This model could be used to justify either extensive public participation or more limited participation, along the lines of citizen juries.

A different model of public participation follows from a stronger claim about the relationship between science and society. Science itself is not an objective 'view from nowhere' but a thoroughly social activity (Jasanoff, 2003, Latour, 1999, Wynne, 2003). If science is not value-neutral then public participation can be conceived of as a means of challenging its value judgements, about, for example, gay sexuality (Epstein, 1996) and electro convulsive shock treatment (Rose et al., 2003). I call this a scientifically-engaged model of public participation. Again examples of such public engagement are fairly rare. They have occurred when an interested public have mobilised and become highly scientifically literate. In many areas, this form of public participation may not be possible as such a public might simply not exist.

These four models artificially separate epistemic and socio-political rationales for public participation. Indeed, I have done exactly what I have just criticised Collins and Evans for doing. To do so is a precarious achievement. Is the experiential-expert who demands a particular rather than a universal framing of a question making an epistemic or a normative point? And might not an AIDS activist who proved as well informed as a scientist be rightly called a non-

certified expert rather than scientifically-engaged? This highlights how public participation as well as scientific inquiry is a social process. The processes change both the questions under debate and those involved in the debate. Many members of the public have become engaged with scientific issues because they feel scientists have got something wrong (be that facts, values or both). They have often found though that in order to be heard they have had to become scientifically literate themselves and to recruit sympathetic scientists to their cause. Thus they might become non-certified experts through their engagement, or they might not. What these models show is that public participation can make different contributions but mechanisms must be in place to achieve these contributions.

A grey area between expertise and laity

Theoretical discussions of the rights and possible contributions of non-experts assume a clear distinction between those with professional expertise and lay people. Indeed, any argument for lay participation assumes that lay people have something to contribute to decision-making that experts cannot. Expert members are appointed to LRECs in virtue of their certified expertise. However, to an outsider observing committee meetings it is not always obvious who the experts and the lay people are.

Whilst LREC Governance stipulates members must sit on the committee either as expert or lay, this binary does not reflect the expertise that members contribute to the review. Lay members are often interested in sitting on committees because they have been health professionals. Of the 23 ostensibly lay members who took part in in-depth interviews 10 were either retired health professionals or were health professionals taking a career break to care for children[17]. A further three were retired researchers. Committee members are aware of a grey area around those with relevant expertise. A research nurse I

[17] Survey data showed that 23% of lay members are over 65. I would expect a good percentage of them are retired health professionals.

spoke to was enthusiastic about having "truly lay people" on the committee but thought that it was unlikely such people would apply:

> I think that you are never going to get a true lay person on an ethics committee, are you? You are always going to get someone who is interested and if they are interested then they probably have insight. And so when is a lay person not a lay person? The answer is probably always. C2

The criteria set by the Governance stipulate the characteristic of the lay membership as a collective, and so it is quite possible for any particular lay person to have experience of the NHS, research, or closely related areas. Lay members I talked to were often quite put out by the suggestion that they did not have expertise. One lay member I spoke to put it like this when I asked her what she had to contribute:

> I have a nursing background. Through being a member of the [Community Health Council] I have a good in depth knowledge of how the NHS functions, hospital functions, things like that...not to the degree to where I can quote verbatim, but I know the things that it is necessary to know. C44

Lay members might be defined as 'lay' in the terms of the Governance. They may also be lay when compared with practicing health professionals and researcher. But compared against most members of the public they would not look so lay.

Conversely, those defined as professional expert members by the Governance may have little expertise to contribute to the evaluation of any particular research proposal. We can ask, following the nurse quoted above, 'when is an expert not an expert?' The answer is quite often. Scientists have different relationships to uncertainty depending on their degree of their specialism (Demeritt, 2001, Collins and Evans, 2002). Many of the expert members on LRECs are not active researchers. The survey I conducted found that only thirteen percent of pharmacist members reported conducting clinical

research on human subjects in the last five years. Medical consultants were the expert members most active in clinical research, with seventy-two percent having conducted clinical research on human subjects in the last five years. Furthermore, health professionals work within their own specialisms. A public health researcher making an assessment of, for example, oncology research can use his/her own experience of research to say if the protocol seems right. However, s/he is not able to make a finely tuned analysis of the scientific merits of the research or the safety of a particular procedure. Indeed, s/he is in a similar position to the lay people on the committee in having to trust the competence and expertise of public health researchers.

In addition to these considerations, new types of expertise emerge through the processes of LREC reviews. Through their experiences on committees and the training they receive individuals become what might be termed 'expert LREC members'. This expertise is reflected in members' skill in reading and assessing research protocols as well as their knowledge of ethical guidelines and standard practice.

Furthermore, 'expertise' is a contested and evolving category that these 'expert LREC members' are actively involved in constructing. Researchers whose protocols must be reviewed by LRECs contest this expertise in, among other places, the pages of the medical press (Harries et al., 1994, Foster and Holley, 1998, al-Shahi and Warlow, 1999, Ferguson, 2001, Boyce, 2002, Savulescu, 2002, Macpherson, 1999, Blunt et al., 1998, Pierce, 1997). This is part of a wider debate about what standards medical expertise should be judged by. It is contested within committees too. As I discussed earlier in the thesis, at one LREC meeting I observed a doctor and a lay member (a trained Bioethicist) constantly disagreed about protocols. During an interview it became clear that the doctor felt the majority of debates were not ethical but scientific ones:

> I do not think having an ethicist on the committee has helped at all. We are not by and large dealing with moral dilemmas, and it leads to very prolonged discussion, often uninformed of any awareness of medicine or research. I have not found it useful, and on occasion found it intensely

> irritating. .... there was a lot of drivel being spoken. You think you could be back at your desk working instead of listening to this, as you feel you are listening to the 'Moral Maze'[18] or something.... to have endless ethical discussions for the sake of it is a waste of time. C19

Whilst such a view is probably attributable, in part, to personality differences, it also demonstrates the extent to which these social processes are constitutive of expertise. Through lay participation in LREC reviews the standards by which medical research is assessed are being altered and are open to contestation.

The capabilities and experience of LREC members are more nuanced than the terms expert and lay member suggest. Many lay members are motivated to get involved on LRECs because of their previous knowledge and experience of health care and medical research. Furthermore, in the process of sitting on the committee they develop experience and understanding relevant to the review. Equally, 'expert' members of the committee are rendered lay by scientific protocols in areas very different from their own specialism. Both expert and lay members though are actively involved in constructing an expertise in ethical review. In the light of this more context dependent reading of laity I now turn to the rationalisation LREC members give for lay participation.

LREC members' understandings of the lay role

Asked in interviews LREC members are almost universal in their agreement about the importance of the lay membership. However, they describe its value as deriving from a number of sources: the need for the review to represent society, to be independent, and the need for patients' experience to be represented. I describe each of these conceptualisations in turn. Each of these conceptualisations makes a claim about what lay members can legitimately contribute to debates: when they can speak with authority and competence (Bourdieu, 1984, Goodwin, 1998). A consultant paediatrician on a committee,

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[18] The Moral Maze is a BBC radio programme in which ethical issues are discussed.

for example, has her statements about paediatrics and paediatric research accepted in virtue of her status as an expert. It is only in the rare situations where two experts in the same specialism make counter claims that LRECs must make judgements about competing expert claims. A paediatrician might, of course, contribute much more to the review. She might, for example, be a grammarian and provide a thorough proof-reading of participant information sheets. However such contributions are not made in virtue of her position as an expert member of the committee.

From this two things follow. First, when members speak outside their area of expertise they have much less authority and what they say is more open to dispute from other members. Second, while it is inevitable that members bring other areas of knowledge and interest it is unpredictable what these will be. Consequently, anything that is thought to be essential to the review ought to be required in the Governance. If a grammarian is thought to have necessary skills then the Governance ought to require one and not rely on the consultant paediatrician having a passion for good grammar. By examining LRECs members' understanding of the lay role, we can begin to assess their potential to contribute to the ethical review of medical research.

Representative of society: 'just more democratic'

Lay members often describe their role as being to represent 'Jo Bloggs' or 'the man on the Clapham omnibus'. They describe themselves as ordinary citizens undertaking a civic duty, 'putting something back in to the community'. A retired business man described:

> (The strength of the committee coming) from the fact that it is hopefully it is a broad based committee. The members being from as wider spectrum of society as possible. It is approval by people hopefully representative of society. C38

Another lay member, the retired nurse quoted above, reprimanded me when I asked her what LRECs would lose if they had no lay members:

> I don't think it is so much what the committee would lose as what the patient would lose. It is the same with losing the [Community Health Council], the patient has lost a lot. C44

So I asked her what patients would lose if there were no lay members on LRECs. In her answer she describes LRECs lay member as being representative:

> Some sort of say in what research is put out and how that research is put out. I think that in days gone by things came about and everyone lauded the fact that they had made breakthroughs in this and that. But there would have been no sort of...there would have been people who would have been the guinea pigs for want of a better word. They wouldn't have been given any details of the research, they would have been, sort of drawn in to it. But would not have had any input into how it was done. They wouldn't have had any input. However, we as lay people can have some input into research. It may be small or minimal. It is valuable. Because at least we are having a say. And I am not from the blue rinse brigade. I am not being derisive when I say that but again, you always had people from the blue rinse brigade. They were the token people there. They were there in name only really. To say that Mrs. Fotheringale, you know, that sort of thing. It was because people such as myself weren't given the credit of having the ability or knowledge to do it. We are fortunate today. Things are getting better rather than worse. I may be, an old lady living in a council house in [place] but I have been to university, I have been a nurse. I have an active role within the health profession, all be it unpaid. C44

As a lay member it is important that she is not one of 'the blue rise brigade'[19]. Her role is to have 'input' into research. Patients themselves might not, thus it is important that someone like them has.

In describing such a position, members (and it is primarily lay members who talk in these terms) stress that the review they undertake is ethical. Scientific uncertainty is the business of the researchers and the expert members. Lay

[19] The blue rise brigade is caricatures of retired middle class women, mostly politically conservative, who do voluntary work.

members make judgements about any ethical uncertainty there might be above and beyond scientific uncertainty. In putting forward such views members stress the procedural importance of lay members sitting on the committees as much as the value of any substantive contribution that might be made (Davies, 2001). Emphasis is on the need for openness and accountability in decision-making (Power, 1997, Smith, 2002, Sharpe, 2000). As one lay member put it: 'The patient might not have had access to read the protocol and question the researcher, but someone like him (sic) has' (C1).

Such a conceptualisation is primarily a socio-political one where lay involvement ensures decisions are made in 'the right way'. The substantive contribution lay members make is described as representing 'society' or 'what most people think is acceptable'. As such, lay participation suggests an extra-scientific model. Some committee members are sensitive to the procedural demands made by this model. Some members I spoke to were disparaging about anyone's ability to represent the views of society or a community (local or cultural). As the expert chair of one committee put it;

> No one can ever be representative of their community, can they? There are people from ethnic minorities on our committee and it is a big burden to place on one person, to say that 'you are going to represent all of the ethnic minorities in (town)' or whatever. C3

Indeed, to invest lay members with this kind of representative power assumes a moral consensus difficult to argue for in Britain today. As discussed above, lay participation can be read as a reflexive response to public mistrust of experts and anxiety about scientific uncertainty (Salter, 2000). However, such a legitimation crisis arises in part from the pluralism of late modernity. It is therefore paradoxical that the response to a legitimation crisis, namely lay involvement in decision making, should assume the very condition, that of moral consensus, that provoked the crisis in the first place.

Moreover, although recent standardization measures have emphasised the importance of equal opportunity in recruitment, LRECs remain far from representative of the population as a whole. In the past LRECs were primarily made up of older white professional men, with hospital chaplains and lawyers vastly over represented as lay members (Neuberger, 1992). The recent drive for standardisation has included requirements that LRECs should aim for a 'balance' of members in terms of age and sex, with 'every effort' being made to recruit members from ethnic minorities and those with disabilities (6.2). As I described in chapter three, LREC members are not representative of the population as a whole. Women now make up about half of committee members and just over half of the lay membership (54%). However, nearly all lay members are white (95%)[20]. Moreover, with nearly 80% of lay members holding a first degree, half of whom also hold higher degrees. This compares with 16% of the working population as a whole who have a first degree or higher (The Office of National Statistics, 2003: figure 3.17). Members who see lay membership as serving a socio-political role are saying, 'You can trust us. We are an ethics committee. We are representative of society.' The reality of LREC membership does not bear out such a claim.

Indeed, we might want to argue that lay members are chosen by LRECs precisely because they are not representative of society, or at least not representative of the wrong sections of society. I asked the chair of a committee about recruitment of lay members. He said:

> I think this is where problems lie, with other places having ladies of leisure thinking they are going to go around the wards, asking the patients whether they are being treated properly. And then, faced with an inch thick of reading to go through, say 'oh God cannot cope with that'. We got it right because we made it quite difficult [to become a lay member]. [Another LREC] took on too many lay people, but all they wanted to do was chat, which they do for hours, whereas the clinicians were saying this is working time. So this is wrong. There are basic points, why are you there, how much time have you got, and how are you going to do it? C38

[20]This is a larger percentage than for the membership as a whole, which is 91 % white.

These last questions are the questions he asks lay members in interviews. He is interested in recruiting members who understand the task in hand and the rules of committee meetings.

Lay members themselves stress their abilities to perform in the committee environment. One lay member described it as having confidence to speak:

> Where it gets most uneven are unconditioned medicos and unconfident or uneducated lay people. If you have a good chairman it would be expected that you pick up on certain issues. It then comes down to lay people who come up to speed in due course. Some do not have the to confidence to speak on certain issues, whereas I do. C21

The retired nurse also stressed such an aspect:

> I am not afraid of speaking. I know how to speak. That may sound like a bit of a silly thing but I have come across people who because they don't know how to talk become...aggressive, for want of a better word. Not aggressive but they get louder and, think that that will make them heard, that sort of thing. So [I am not like that] I think that I know how to speak. C44

So while it may be desirable to have lay members we can think of as representative of society, we do not actually want them to be 'too' representative of society. One way to ensure members were representative of society, for example, would be to elect them or alternatively to select them like jury duty. That way, at least, they would have a mandate for their role of representative.

Without such a mandate lay contributions are vulnerable to being trumped in the course of LREC deliberation by appeals to professional authority, notwithstanding this generalised idea of the procedural value of lay involvement. For example, I attended a number of meetings where research proposing to use stored tissue was reviewed. In light of recent scandals this might have been an area where lay members could convincingly argue that society had ethical

problems with such research (Andrew Irving Associates, 2002, O'Neill, 1996). In one telling case a lay member felt a research protocol should be rejected. The rest of the committee disagreed with her. She asked them, 'if it comes out in the local paper that we have given this ethical approval can I explain myself to my next door neighbour?' An expert member countered that the research complied with all recent guidelines and was normal practice in that research area. The lay member was unable to have her misgivings recognised as a sound position from which to challenge professional guidelines.

Independent from the medical profession: 'there as an outsider'

Some LREC members see the value of lay participation as deriving from their ability to review protocols as an outsider; lay members are able to contribute because they are only 'tourists' visiting the world of medicine. Their independence allows them to see research protocols with 'fresh eyes', to 'take two steps back' and 'ask seemingly obvious questions that sometimes turn out to be important'. Asked what lay people contribute, a research nurse replied:

> General questions. We are used to the system but they are not. I tend to think that something is alright, normal and just go along with it. You need someone who doesn't know about it to ask the questions. C7

These general questions can be about ethical or scientific issues and indeed tend to be about ostensibly scientific issues, such as why participants need to come off other medication during a particular drug trial. This conceptualisation of lay participation stresses the difference lay members make to the outcome of the committees' review. It also relies on an implicit assumption that independence is a good thing. As with the view that lay members are representative of society, lay membership is conceived of as having both a procedural and a substantive value.

Such an understanding of lay involvement stresses the uniqueness of the lay members' contribution by virtue of their lack of expertise. I have already

problematised this expert / lay distinction. With over a quarter of all lay people sitting on an LREC for over five years (26%) we can question the extent to which they can be described as having 'fresh eyes'. In her analysis of lay membership on Multi-centre Research Ethics Committees, Duckworth (2002: 7) argues that '(it) is because they are 'unworldly' in this scientific setting that they provide an effective counterbalance to the professional membership'. To describe lay members as a counter balance in this way implies there is weight to their contribution. Though the ideal of lay independence may be valued, lay members are not in practice thought to be credible judges of scientific aspects of the research. They are described as asking questions, not as being able to answer them. Their role is not comparable with that of a jury asked to judge between competing expert claims. Lay members are not described as the arbiters of the review but as prompting expert members to perform a better review. Equally, within this view, lay participation is not rationalised in terms of any expertise that lay members might contribute. It is precisely their lack of expertise that is thought to make them useful members.

This conceptualisation of lay members as independent from experts, that is without expertise, fails to acknowledge that lay members can come to the LREC as experts in their own right and certainly develop expertise through sitting on the committee. Furthermore, such a conceptualisation limits the potential contribution lay members can make. Any contribution is contingent on expert members judging their 'obvious questions' to be relevant, and often they do not. One nurse I interviewed explained her frustration at 'off the wall questions'. A lay member had argued that rather than requiring patients to make additional visits to hospital to undergo tests, the tests should be carried out in the patients' home, a suggestion the nurse thought ludicrous given both the equipment required to perform the tests and the resource implications for the NHS:

> He didn't understand the practicalities. Doing those requires a piece of very expensive and enormous equipment. You just could not move it around like that. And that equipment is in demand. If you could transporting it around you would be deny access to patients who need it as part of their clinical care. It is all a bit ridiculous. C11

Equally, questions that lay members raise concerning more explicitly ethical issues are often judged by expert members to fall outside the remit of the review. As this expert member said in discussing a question a lay member had raised:

> I thought that the points that he was raising were very important but they were almost unanswerable questions. C13

Like the professional member who likened the Bioethicist and LREC deliberation to the 'Moral Maze' radio programme many experts view the review in terms of their own bodies of professional knowledge. Without an explicit role it is hard for lay members to challenge these understandings.

In the face of this professional rendering of ethical review, lay members become what we might call expert lay members, that is, lay members who are experts in ethical review. So for example, lay members are very likely to refer to ethical guidelines in interviews. When I asked one lay member what makes research ethical, she answered:

> Well. To make it ethical it has to adhere to the Helsinki declaration or the relevant bits and pieces. C4

For this particular member, it does not feel that she is really at home with the Helsinki declaration and the other 'relevant bits and pieces'. What her answer shows is that even where members do not feel particularly confident, the documents they learn about on their training seem to offer them a platform from which to contribute to ethical review. A professional member, a nurse academic, described the contribution he thought lay members could make:

> There are a number. For starters they examine the thing...most of them take it very very seriously, possibly more seriously than most of the non-lay people, especially the participant information sheet and thing. Partly they

are looking at it from the lay perspective so they seeing what it would be like to... they are very good at going through the information sheets saying well I am not sure that this is clear, picking up on...picking up on things about the language. Sometimes they pick up on things that can be pernickety and you think, come on. They do say things that are not relevant. But that has improved. They have started to realise what's important I am not sure whether that came directly from the training or not. I find them saying things and I think god that's a really important point. I wish I'd said that. C25

Through training and experience on the committees lay members develop the skills of conducting an ethical review. This is both inevitable and desirable. However, it compromises the conceptualisations of lay members as an independent in the review.

A proxy patient: 'if I were ill I wouldn't want that to happen'

A third rationale given by members is that lay people contribute a better understanding of what it is like to be a patient. A teacher taking a career break explained:

> Lay people are there to protect patients. I think that we have an understanding of what it is like to be a patient, of what patients need and what they might be feeling when they see a doctor. C9

On this view lay members are valuable to the review because they are able to contribute an experiential knowledge that differs from the technical knowledge contributed by expert members. In contrast to the conceptualisations given above, lay members are understood to have a distinctive position on LRECs through knowledge gained as a lay person. Such an understanding of lay participation grants lay members the competency to challenge experts' technical definitions of the review.

Lay members use their experience of being patients or living locally to inform the review. Lay members describe how patients have very different

perceptions of their illness, treatment, and medical research than professionals (Mann, 2002, Featherstone and Donovan, 1998). One lay member described to me the objections another lay member on her committee had to the wording of an information sheet:

> She said 'you know if I was presented with this information I wouldn't like it. I don't like the word cancer in there'. The information sheet said 'you have been chosen for this research because you might have cancer'. And to a medical person cancer isn't a scary word but to a lay person it is. If you got an information sheet that says that whilst you're waiting for a diagnosis you'd be petrified. She said that it was wrong. And she is right. C20

Lay members are also sometimes imagined as having knowledge of the local area pertinent to the review. In one meeting I observed a lay member objecting to a protocol that required patients to make a number of extra visits to the hospital where the LREC meeting was being held. Talking to her about it afterwards, I was told:

> This hospital is not well served by buses. I know I have to come here each month for the meeting. If you miss one you can be waiting nearly an hour for the next. On paper the extra visits might not seem a lot. If you have a car, fine. But if patients have to travel by bus then you are asking too much.
>
> C44

Such a positioning stresses the substantive contribution lay members can make by virtue of their everyday experience. Lay members are not thought to have scientific or quasi-scientific knowledge but phenomenological or experiential knowledge with which they can credibly challenge expert members. Here lay membership is conceived of along the lines of the experiential-expert model of public participation, able to contribute in virtue of their expertise in everyday life.

Lay members are not the only committee members claiming to have this sort of knowledge though. In an interview with a lay member, I discussed a

debate within her committee on whether a participant information sheet for some breast cancer research was too technical:

> Well, they [an oncologist and nurse] were saying that this is a well informed group who want all the information. I was thinking about my mother-in-law who had breast cancer. I really don't think that she would have understood it [the information sheet]. But that's just her. These doctors are on the wards everyday. They know lots of these patients. C22

Even with a personal experience of the illness being researched, this lay member did not feel she had the competency to challenge the experts' judgement. Although lay members have experience of being patients, they do not have a monopoly on understanding patients' experience. Indeed, expert members, many of whom have day to day dealings with patients, can and do claim more expertise in understanding public understandings of medicine and illness.

Can lay members contribute to LREC decision making?

It takes more than simply inviting lay members on to a committee to ensure that they contribute to decisions making. Admitting his biases, one member of a committee, a nurse academic, described some of the difficulties of ensuring lay members are able to contribute:

> ...medics are much more eloquent because their training teaches them to be. I have heard people knock their scientific knowledge but they have better knowledge of things that come to the committee [than lay members]. They have more understanding than most people. Most medics I know have a fairly good understanding and they have really good memories. So they remember what a RCT is. They are eloquent. they have knowledge and they have status. That holds weight. It is very difficult to divorce yourself from the fact that someone has status. As a nurse I have an inbuilt dislike of medics. But it is very difficult to divorce yourself from that. Medics, for starters, have....the power within the committee is very different. I notice sometimes when lay people talk they aren't always listened to and they can be dismissed. I think [the Chair] is very good at trying to include people but

now and again some of us say something and either because he disagrees or someone else disagrees we end up getting shouted down. And I think most of the medics on the committee are not....they are nice people. It isn't a conscious thing. There is a real difference of power on the committee. I think that has an impact on the decisions that are made. In terms of where the sympathy lies. C25

In order to ensure a role for lay members on LRECs such power relations need to be addressed.

To be more effective lay members need a more clearly defined role. Observation of committee meetings showed that experts' professional understandings of the review are naturalised. The risks of medical research and the standards applied in its review are rendered as technical ones. In the face of a powerful medical profession (Goodyear-Smith and Buetow, 2001), lay members rely on their authority as 'expert LREC members' to make their contributions heard. Such authority derives from a working knowledge of the remit and guidelines. Consequently, 'expert' lay committee members reassert rather than challenge the professional standards used to assess the ethics of medical research. LREC Governance (Department of Health, 2001a) provides no guidance on the role lay members should play in the review. There is consequently no clear contribution lay members make as lay members per se. In the face of powerful professional understandings of expertise and the apposite standards to be applied, lay members have little authority and competence with which to challenge expert interpretations of the review. Within LRECs lay members are able to affect the review in spite of, rather than because of, their status as lay members.

Conclusion

Local Research Ethics Committees are by no means the be all and end all of ethical medical research. Parliament, the researchers' offices where protocols are written, the wards where patients are recruited, and the media where scandals are exposed are all implicated, in each of these sites experts and non-experts

interact and contribute differently. On LRECs, though, non-experts are described as bringing openness, independence, and democratic decision-making. These are all claims that are made about public participation more generally. In this chapter I argue, it is not enough simply to allow lay people to sit at the table. To be effective, participation requires clear aims and strategies to deliver those aims. For example, conceived of as 'representative of society' lay membership fits the model of extra-scientific public participation. For this model to be properly implemented antecedent issues would need to be addressed. We might, for example, want to remake LRECs in the vein of citizen's juries. Certainly, scientific questions would not be addressed by lay members, instead they would assess the elements of research concerned with social values. Moreover, such a model requires a democratic recruitment process. We could argue that local politicians or community leaders should sit on LRECs, or that members of the public should be selected as they are for jury service. No model of public participation can be taken off the shelf ready for use. What these models do is remind us lay people can contribute different things in different ways. When we fail to address what we want the public to contribute and how, we risk wasting peoples' time and endangering further the relationships of trust between experts and non-experts.

The increased calls for public participation cannot be understood outside of the wider context of changing expert / lay relationships. Where once the public trusted experts in virtue of their expertise, the relationship in late modernity is marked by a more complex and contested relationship (Beck, 1992, Giddens, 1990). Collins and Evans (2002) assume public trust in experts will follow once a theoretically sound foundation of expertise has been established. The problem of legitimacy they set out - who <u>should</u> be allowed to make decisions, does nothing to answer a wider crisis of legitimation - who <u>do</u> the public believe and why (Habermas, 1976).

It seems to be assumed that public trust will follow from having lay people involved. But as expertise and trust in expertise are problematised it follows that so is laity. Effectively addressing these changes and learning to make good and fair decisions will be as complex and contested as these relationships. These

questions about the relationships of trust between experts and the public are not ones that we have the luxury of ignoring. As public participation takes many forms (Renn et al., 1995) examining a single case study cannot furnish us with a universal model. The example of LRECs is nevertheless valuable in making sense of the complexities and contradictions of public participation. Despite a near universal acceptance of the idea of lay participation, the actual role of lay members is vague and inchoate. As I have served as a lay member on a committee myself I am well aware of the huge commitment (not least of time) and integrity of lay members. I argue, though, that without clarity about how these members should be involved their potential contribution is diluted. This represents, at the very least, a huge disservice to the lay members themselves.

Chapter 9

Conclusions and postscript: LRECs and emplaced bioethics

I began this thesis by arguing that in order to make better, more ethical decisions, we are required to pay close attention to places in which such ethical deliberations are had and decisions are made. In doing so I have challenged a number of commitments that underpin the present tenor of debate about, and politics of, bioethics. In particular, I have criticised an approach to these issues which assumes that they are universal in nature and can be identified and solved through the application of universal principles and logical reasoning.
Contrary to my own, this other approach posits that to make better ethical decisions we need to clarify relevant concepts and arguments. This approach assumes that the application of ethically acceptable decisions are either straightforward and neutral or, at the very least, something beyond the remit of ethics proper. I describe this as the fallacy of application.

As the title of this thesis suggests, I take the 'applying' of ethical principles, or indeed regulatory standards, as active and contingent social achievements. Ethical decisions are made through people, places, and things; not merely by recourse to abstract principles or ideals. The who-what-when-where-how of ethical deliberation and decision making is not extraneous. It is fundamental; at the crux of both the achievement of a decision and what we need to understand in order to comprehend a decision. I have argued in this thesis that we need to reject the notion that ethics is something pre-existing to be applied universally and re-conceptualise ethics as something that ought to be "emplaced".

CONCLUSIONS

To this end I have produced an account of the emplaced ethics of one particular site of ethical decision making. These ethics committees, gate keepers in the research process, make decisions about many of the same types of issues found in academic Bioethics literature. As each of the substantive chapters has its own conclusion I do not intend to recap each and everything I have said about LRECs and their emplaced ethics here. Rather, in this conclusion to the thesis, I wish to make some more general points, first about emplaced ethics and then about the policy implications of this research project.

I begin by looking at what characterises LRECs' emplaced ethics . In chapter two I argued that Bioethics is full of geographical metaphors and that a geography of ethics could help flesh these out. I examine what this particular study has to say about questions of distance, locality, and community. I then turn to the notion of emplaced ethics more generally. I argue that an emplaced ethics offers a means of fleshing out situated epistemology and examine the partiality of the account I have produced. I end this concluding chapter by examining the policy implications of the research, setting out both a revolutionary and a revisionary agenda.

LRECs' emplaced ethics

It has been the aim of this thesis to give an account of the ethical deliberations of one site where ethical issues arising from medical research are identified, discussed, and settled. Local Research Ethics Committees have an important role in regulating ethical aspects of medical research in the UK. Research Ethics Committees, local or otherwise, are a contemporary solution to a contemporary set of pressures. An emerging global market in medicine and medical research requires a 'harmonisation' of national regulation to smooth the way for a global pharmaceutical industry. This imperative has driven standardisation, as has the demand from researchers for a more predictable review. The ethical review system promises standard protection for researchers (who demonstrate before research starts that due care has been paid to the ethical aspects of trials) and for patients who take part in those trials. The UK REC

system is a particularly interesting site for investigation because it has been heralded as a model for the rest of Europe to emulate (Department of Health, 2005).

Moreover, this model of anticipatory ethical review of research by ethics committee is spreading beyond medicine to other research contexts. The UK Economic and Social Research Council recently undertook a review of ethical review procedures for social research. Whether its intended outcome was mimicking of the medical model or not, there has been a mushrooming of such committees in universities across the country. A study of LRECs then has much to contribute beyond analysis of its own immediate circumstances.

LRECs are of course spaces in which ethical decisions are made. However, I have argued that in order to make sense of these committees' emplaced bioethical discussions and decision making we need to understand the committees as professional spaces and spaces in which, what I have called, mediated self-regulation is performed. They are, importantly, spaces for the performance of expertise and for the performance of accountability. So, for example, that these are professional spaces enables us to make sense of how committees view other medical professionals and patients who are subjects or potential subjects of medical research. Being a medical professional invokes certain types of relationships. As I argued in chapter seven when discussing locality review, in asking LRECs to make an explicit judgement about whether a researcher is suitable to conduct researcher or not, the Governance is asking for the near impossible. To make such an assessment would involve challenging a fellow professional's expertise and conduct. As the treatment of NHS whistleblowers has shown, publicly denouncing fellow professionals is a difficult and high risk activity. There are established procedures in place for medical professionals to question others' professional conduct. An ethics committee is not one of them.

The professional nature of the space of LRECs and their role as spaces of accountability are also important in understanding their enactment of informed consent. As I have discussed, the requirement of an informed consent from

subjects in medical research has become the sine qua non of ethical medical research. I have argued that informed consent acts as a boundary object. The emphasis placed on consent by LRECs is to a certain extent key to enabling action across a number of different social worlds. Informed consent is stable enough to make sense across and to enable action between these different worlds. However, LRECs' informed consent is shaped by the duties of medical professionals, to protect patients, and by the demands made by current notions of accountability.

Medical professionals have traditionally viewed decision making about ethical issues to be an important element of their professionalism. Increasingly self-regulation of the profession is coming under attack. Ethical review is required to construct an openness and transparency to what are essentially discrete and intimate exchanges. New demands for 'open', 'transparent', and predictable decision making translates into standardardised application forms, participant information sheets, and a intolerance of local variation. The consent exchange is distant in time and space from the LREC committee room and so the material that mediates between the spaces of review and consent become fetishised. Participant information sheets and consent forms take on disproportionate meaning and occupy an indefensible (albeit understandable) position in the review LRECs perform.

The nature of expertise more generally is an important thread that runs through the thesis as a whole; the expertise of medical professionals, of medical researchers/scientists, the emergence of the Bioethics as a domain of expertise, and indeed the foundation of my own (social science) knowledge claims. As I have argued in chapter eight, expertise and indeed laity are constituted through demonstrations of expertise and through what Gieryn (1995) calls boundary work. LRECs are one site of the production and performance of medical and scientific expertise and an investigation of them opens one window on the relationships between science, governments, and society.

Local knowledge is often contrasted with expert knowledge. An opposition which draws on how, as discussed in chapter five, expertise often

relies on creating universal spaces such as laboratories and on representing the world as spatially undifferentiated. Being an expert often involves being able to make knowledge claims and decisions across space and time. In this thesis I have tried to avoid this construction of an opposition between local and expert knowledge. By using a notion of emplaced ethics I have described both expert and non-expert contributions as contingent and context dependent, assuming an epistemology of situatedness. I have examined locality as it is defined and enacted in the committee system. In chapter seven I described the definition given by the Governance and examined how this is worked out in the review LRECs perform. What is interesting is how locality has, despite a commitment to lay participation, become identified as a bad thing. Local variation, it is assumed, has not come about because the local community has had an input rather it signals a conflict of interests or a review that is in some other way indefensible. The qualities of mechanical objectivity have become valued above all others.

As I describe in the introduction of this thesis, when I selected committees to take part in the research I was especially interested in observing committees in particular areas. I observed committees in localities of particularly bad health and places that had been at the centre of national scandals. I also went to areas of North East England where there had recently been 'race riots'. Medical research has a racial as well as a gendered history and I was interested to see if these particular localities impacted on what happened inside the committee rooms. As I have described in chapters seven and eight, there is no real representation of local communities on committees. As a result, local issues, such as those of poor local health or racial tensions, do not contribute to ethics committee decisions. In the committees I choose, I searched for examples where local socio-political circumstance might affect review outcomes. I found none.

However, I found that experiences of recent scandals did impact on how committees viewed me as an observer. I observed two committees operating in areas whose names had become synonymous with recent scandals. The committees though treated me very differently. One of the committees was eager to show they had nothing to hide. I was sent all the applications before the

meeting, I was welcomed to the committee, and members were happy to discuss the impact the scandal had had on health service delivery in the area. In contrast the other committee, although I was allowed to attend, was very suspicious of my presence. I was asked to sign a confidentiality form and asked to leave the room at one point in a discussion. In a sense then we might say that the local NHS context that the committees operate in affects the review, if not the wider socio-political context. Such a finding is in line with the overall description as LRECs as medical professional spaces.

In this discussion of locality I am not arguing that local relationships and local knowledge are inherently less morally perilous than distant ones. 'Local knowledge' is not necessarily any truer or more authentic than expert knowledge. Rather I am arguing that we ought to seek to understand the roles, materials, relationships, and rules through which ethical deliberation and decisions are enacted, whether they be local or distant. I have argued that understanding ethics as emplaced (that is context dependent, social and contingent) is a way of fleshing-out notions of situated epistemologies.

By producing an account of LRECs and their emplaced ethics, I have shown that the places in which ethical principles are applied are fundamental to understanding and thus improving the decisions that are made. For LRECs it is the immediate locations, the structures and rooms of the NHS, that have most impact on decision making. The construction of LRECs is such that wider local issues such as particularly bad health do not get aired. However, it is not better recourse to reason and principles that are wanted in these debates. The place - rooms on NHS property, the people - and the commitments they have made to their profession, and the materials - such as paperwork, are the particulars through which problems are discussed and deliberations are performed. Ethics is not extricable from these particulars but constitutive of them.

Understanding LRECs in this way facilitates an understanding of the nature of ethics that challenges the fact-value, science-ethics dichotomies of the Enlightenment legacy. LRECs are spaces designated as ethical spaces, but this quarantining of ethics is a hard won, always ongoing battle. Ethics cannot be

separated from the rest of life. It is everywhere. How, why, and with what consequences some places are called ethical ones and others not, is a fundamental and pressing question.

Emplaced ethics

In a schema of emplaced ethics, academic or professional Bioethics is one view among many. It is not a blueprint or a paradigm case against which we ought to compare all other (lesser) deliberations and decisions. It is just another mode of ethical reasoning which needs to be 'put in its place(s)'. The attempts to represent its own view as universal, 'a view from nowhere', ought to immediately make us suspicious that we are being duped by, as Haraway says below, a god trick. Academic Bioethics is itself a situated and thus socially produced knowledge. The places of Bioethics have traditionally been university offices and philosophy seminar rooms. Increasingly, though, it is becoming enacted in government committee rooms, in medical school lecture halls, and in our (broadsheet) newspapers. These new places of Bioethics bring with them new demands, new audiences, and new materials of decisions making. As Harris (2001), among others, has noted, Bioethics is changed as it is practiced and reported in new places. These new emplacements of Bioethics, I argue, ought to make us more suspicious of attempts to represent academic or professional pronouncements as universal. We ought not, though, engage in a project of purification but an investigation of these new emplaced Bioethics. Place, I argue, cannot be treated as epiphenomenal.

It is not, though, that place provides a neat objective category with which we can shore-up our newly socially contingent notion of ethics. Space is not absolute. Place is not unitary nor pre-existing. Both are actively constituted through their performance by actors (human or otherwise). They are also actively constituted through the methods by which social scientists choose to investigate and represent them. I return to this issue below when I reflect on the implications of my own methods.

Understanding ethics as emplaced follows from a commitment to situated epistemology. Ethical 'knowledge', as much as any other knowledge, must be understood as context dependent: understood in a way that enables us to escape the Enlightenment confines of so many dualisms (subject-object, society-nature, fact-value, science-ethics); of an Enlightenment epistemology that values above all else coherence, reason, and certainty. No one states the case better than Haraway (1991, 195):

> I am arguing for politics and epistemologies of location, positioning, and situating, where partiality and not universality is the condition of being heard to make rational knowledge claims. These are claims on people's lives; the view from a body, always a complex, contradictory, structuring and structured body, versus the view from above, from nowhere, from simplicity. Only the god-trick is forbidden.

Understanding knowledge as situated rather than universal challenges us to flesh out the 'situations' of knowledge, to flesh out the emplaced nature of ethical deliberation and decision-making. This thesis is one example of a response to that challenge.

As I have already said, neither space nor place are pre-existing, absolute, nor unitary. Rather they are actively constituted and performed. One way in which this is so is through the interventions and representations of those who choose to study them. All knowledge, including my own study of LRECs, is situated, partial, and open to contestation. I want to reflect here on the partiality of this study.

My aim with this piece of work was to make sense of LREC practice and in order to do so I used intensive qualitative methods to produce an account of the actual spaces of LREC deliberation. I was interested in making sense of LRECs' emplaced ethics in their own terms rather than as a poor reproduction of real (academic) Bioethics. I was interested in providing an alternative to the analysis that LRECs behave how they do because of a lack of understanding, be that a lack of understanding of science, bioethical principles, or the Governance

they operate in. The study was prompted by a huge surge in attention to LRECs from the research community, pharmaceutical companies, and the government. Attention which, by and large, had been aimed at standardising LRECs and their practice. I was interested in the effect such standardisation was having.

While it was for good reasons, my methodological commitment to the space of the committee room inevitably reproduces some of the blind spots of LRECs themselves. Importantly it reproduces the absence of debate about how researchers, and more importantly the pharmaceutical companies who fund research, are the real audience for and driver of ethical review and its recent reforms. LRECs themselves operate as if the subjects and potential subjects of research are their audience. Of course, both rationales are important to understanding LRECs. However, patients have largely remained ignorant of, and silent about, ethical review. Another consequence of my methodological commitment is the way in which LRECs can sometimes come across as hermetically sealed spaces. This is though, by and large, an accurate representation of a process which has received so much recent effort to standardise it. The methodological commitment that enabled me to produce this account of the emplaced ethics of LRECs though, are as fruitful as they are partial. Absences from my own account of ethical review can to be supplemented by others work, such as that of Abraham and Reed (2002, 2003).

Policy recommendations

There are two approaches to assessing the policy implications of this study. On the one hand we can think of what the research teaches us irrespective of the contexts, agendas and legal frameworks within which LRECs have evolved and so produce a more revolutionary set of recommendations. While these are worthwhile in themselves, more revisionist recommendations are perhaps more helpful in the sort term. Certainly, within the existing system of LREC review, improvements could be made by an empirically based engagement with LRECs' emplaced bioethics. Centralised requirements and regulatory standards are a fact of life. However, they might better be

implemented if we develop understandings of the actual spaces, and the roles and relationship invoked in these spaces, in which they are to be applied. I turn to each set of recommendations, the revolutionary and the revisionist, in turn.

Revolutionary recommendations

Recommendation 1.1: Remove consent documentation from ethical review.

The review of participant information sheets and consent forms is currently over-emphasised in the ethical review of medical research. It is erroneously conflated with lay contribution to ethical review. In order to address this, the review of 'consent documentation' should be removed from ethical review. Badly written communication to and information for patients and users of the NHS is a wider issue and ought to be tackled as a whole. For example, a review of information sheets by literacy experts would be well placed and ensure clarity and readability in participant information sheets.

Recommendation 1.2: Open up access to research protocol.

The LREC system remains essentially paternalist with no proper channels for lay or community voices. The challenge will be to respond appropriately when patients refuse the categorisations assigned to them, as has happened in some examples, such as research into AIDS drugs and treatment for nCJD (Epstein, 1996, Dyer, 2003). No bureaucratic system alone can deliver non-paternalist medical research: strong civil society, patient and other interest groups are needed to enable participants in research to challenge assumptions made about them. The present system, though, which allows secrecy in the name of protecting commercial interests, disadvantages such groups. Rather than expecting participants to be reassured by assurances of scrutiny by an ethics committee, participants themselves and their chosen representatives ought to be able to scrutinize research protocols.

Recommendation 1.3: Replace LRECs with expanded scientific peer review.

The only conclusion to reach about LRECs, based on this research, is that they should be abolished. This is in no way to devalue the work of committee members and administrators who undertake their work with integrity and commitment. The system though is flawed.

I have argued throughout this thesis that facts ought not be separated from values - science from ethics. LRECs create a spatial quarantining of ethics. By abolishing LRECs and requiring ethical issues be addressed as part of scientific peer review, the hybridity of these issues would be addressed and the time-space of science would no longer be excluded from ethical review. Such a recognition and inclusion is revolutionary because it is unsustainable within current conceptions of expertise and thus creates the possibility of real engagement and contestation of the relationships between science and society.

Given the recent emphasis on establishing a standard ethical review system, the recommendation to abolish LRECs is unlikely to find much favour with government. Indeed even if they wanted to they are now bound by a legal requirement stemming from Europe. In light of this, I turn now to a set of more revisionist recommendations which recognise the context in which LRECs operate.

'Revisionist' recommendations

As these recommendations are made in light of the contexts in which LRECs are evolved and operate I want to begin by outlining the changes that occurred during and after I completed my fieldwork.

The fieldwork on which this thesis is based was undertaken between May 2002 and February 2004, a period of huge change for LRECs. The body established to co-ordinate research ethics committees, the Central Office for Research Ethics Committees (COREC), had been in existence for less than two years and the Governance Arrangements for Research Ethics Committees[21] had been published the year before the research started (Department of Health, 2001a). The impact of these two structural changes was being felt by LRECs

[21] Hereafter 'the Governance'.

across the country while the fieldwork was being undertaken. Committees were increasingly coming under central control and feeling the need to be able to justify their decisions. Some within the system were experiencing this as quite an insecure time. Moreover, the system was preparing itself for the implementation of the EU Clinical Trial Directive 2001/20/EC. This happened when *The Medicine for Human Use (Clinical Trials) Act 1031 (2004)* passed before both Houses of Parliament in April 2004 and came into force on 1st May 2004.

Since I completed fieldwork RECs have faced still further changes. At the time of the fieldwork there were 218 LRECs listed on the COREC website. The number of committees has been drastically reduced and their organisation changed. There are now (October 2005) 190 RECs in total. A system of accreditation has been introduced for committees. Indeed, RECs are no longer Local or Multi-centre RECs, but recognized Type 1, 2, or 3 RECs or Authorised RECs. Recognized Type 1 RECs are able to conduct ethical review of research involving healthy volunteers. Recognized Type 2 are committees that are able to review medical research in line with the requirements of the Medicine for Human Use (Clinical Trials) Act within a single geographical domain. Recognized Type 3 committees can review such research for more than one geographical domain. Committees that are not recognized are called Authorized RECs and can review research other than clinical trials of investigational medicinal products.

Furthermore, COREC is now part of the National Patient Safety Agency and its robust director, Professor Terry Stacey, who has done so much to implement changes in the system, has retired. COREC has introduced a central allocation system for applications and new standard operating procedures for RECs (National Patient Safety Agency, June 2005). The organisation also produces monthly on-line publications 'REC co-ordinator Bulletins' and 'RECs in the news' and a quarterly on-line 'From the Hub' newsletter. In November 2004 an Ad Hoc Advisory Group[22] was set up by the Department of Health to investigate the operation of RECs within the NHS. The group reported in May

[22] Here after the Group.

2005 (Department of Health, 2005)[23]. I return to its report and the recommendations made below.

Although these are obviously turbulent times for research ethics committees, the issues described in this thesis are enduring ones. Medical research involves the coming together of many different social worlds: medical professionals, government, business, electorates, individuals who are suffering from ill health, and so on. Such socio-political and scientific negotiations will always be difficult. The questions I have explored in this thesis about regulation of expert decision-making and professional responses to scrutiny are not going away. The professional status of scientists and doctors increasing fails to forestall external scrutiny. Moreover, patients are less likely to act as passive guinea pigs in medical research. If anything goes wrong these patients may well pursue legal cases. As the stakes of medical research are raised, so too are the stakes of its ethical review.

<u>Recommendation 2.1: Differentiation of research</u>

An important issue raised by my study is the distinctions to be made between different types of research. Drug trials have different ethical issues associated with them than qualitative research. Research into chronic diseases has different issues than research conducted at the very beginning or very end of life. The EU Directive 2001/20/EC concerns only drug trials, but in Britain the same system has been implemented to cover all research taking place in the NHS. There is then, while remaining within the EU requirements, the freedom to make distinction between ethical review of different types of research. Such an amendment to the system would more accurately reflect the ethical difference attendant on research.

[23] Here after refereed to as the Report.

Recommendation 2.2: Inclusion of participants in the audience of LRECs

In the Report the Advisory Group suggests that the REC system has been successful in rectifying the past problems of slow and inconsistent review and in the implementation of EU Directive. However, the Report finds that COREC has not been as successful in its communication of these successes. The Report says many of the submissions they received from researchers criticised the research ethics committee system as time consuming and overly bureaucratic.

Researchers, it seems, still feel it is too difficult to obtain ethical approval for research (2.4). Indeed, that view is confirmed by a recent cover story in the *British Medical Journal* (figure 9.1). The Group felt that, on the whole, these complaints were based on outdated perceptions of the REC system. They recommend that COREC needs to market itself and the REC system to researchers more effectively (2.5).

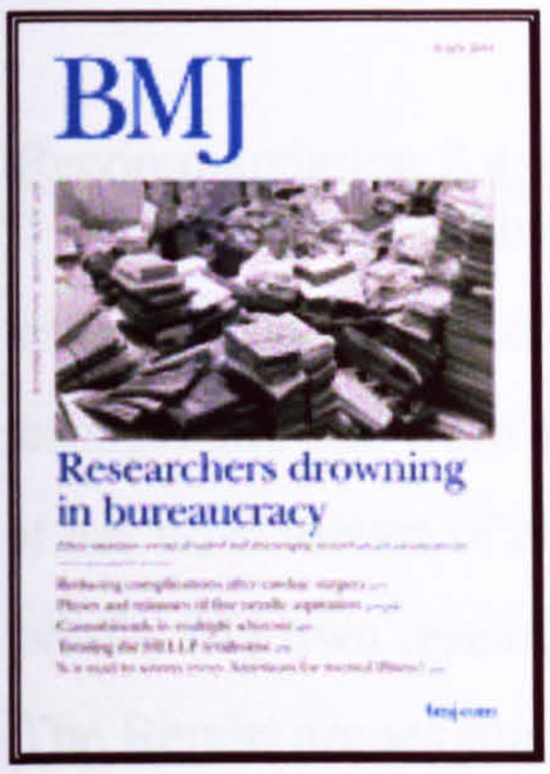

Figure 9.1 'Researchers drowning in bureaucracy' BMJ cover 31st July 2004
Confirming the Reports assessment of researchers views of RECs

The Report's framing of the recent changes in the REC system confirms that it is researchers to whom RECs are primarily accountable, even though they were initially conceived of as a response to mistrust by the lay public. REC reform is driven primarily by the demands of the research community. In this respect, the ethical review they perform remains a form of self-regulation; of system of ethical review should be extended to potential subjects as moves to reframe participants as well as researchers as the audience for LRECs.

Recommendation 2.3: The reframing of locality

The question of whether a local knowledge and relationships, such as relationships between committees and researchers are a good thing or not is a difficult one. There will always exist a tension between locality and independence. The value of local relationships, though, should not be dismissed before it has been given proper consideration. Local review does not automatically result in conflicts of interest and it offers some advantages. Primarily, it offers an ethical review that is not just about paperwork. If committee members have local knowledge it provides them with a means to challenge the account researchers give on paper. As I described in chapter seven, locality review of previously approved research is not an effective way to include these strengths in to the system. Local knowledge just cannot be standardised in this way. The system would benefit from proper consideration and defence of local differences in ethical review.

Recommendation 2.4: Clear aims and strategies for lay participation

The Report observes that the current membership is drawn from 'a relatively narrow spectrum of society, members tending to be professional in background and from an older age group.' (3.7). The Group reports that although it has no evidence of ethnic mix, it is sure that it does not represent society as a whole. My own research suggests that LREC members are predominantly white. The Report argues this is ethically relevant:

> In ethical terms this is relevant if, for instance, different religious and other perspectives are to be taken into account. In interpreting ethical principles in practice RECs should be broadly representative of the community. (3.7)

The Report goes on to say that by replacing the voluntary system RECs might be able to recruit members more representative of society (4.12). The Group's gesture towards the need for more representative RECs is admirable. For them to have any meaning though they need to be a little better empirically informed and directed. The recommendation for payments to be made to members as a means of recruiting more representative lay members only addresses half of the equation. There is, as I outlined in chapter eight, an understandable feeling

among committee chairs that they want the 'right' kind of members. Certainly, it is hard to square the drive for standard review with a recognition that religious and 'other perspectives', whatever those might be, may be relevant.

The Group also states that RECs 'must represent the public interest as well as patient perspectives on research' (5.7). However, my research finds that they do not even manage to represent the patient's perspective, apart from as the imagined patients of the professionals' discourse. Thus it is difficult to see how this kind of vague aspiration might be achieved. In order to enable lay members to participate in ethical review the arguments I presented in chapter eight need to be addressed. Lay members ought to, and could, male a real contribution to ethical review but merely having them at the table is not enough. The REC system needs proper strategies to be developed and implemented to ensure lay members are able to contribute to decision making.

Recommendation 2.5: Recognition of a grey area between science and ethics

The report re-asserts that ethics committees should not conduct any scientific assessments of research. There is a perception among researchers, the Report says, that committees 'did not understand their research or had preferences for certain clinical research methodologies' (3.2). The Group comments that while this perception may be valid 'it risks missing the point that RECs are not, and should not be, responsible for detailed scientific review' (3.2). The report concludes that RECs should 'deal with the ethical rather then scientific review.' (4.5). Accordingly the application form should 'give more space and attention to ethical issue' (5.4). As I discuss in chapter five, the relationship between science and ethics is often not as straightforward as the Report assumes.

To resolve problems of a scientific nature, the Report advised that a Scientific Officer be established within COREC 'to support the work of committees. They might undertake much of the preliminary assessment required and review reports. Chairs, for whom it is a major burden, currently undertake this work' (5.9). When RECs receive non-peer reviewed applications they could refer them to the Scientific Officer (3.2). The creation of such a post might, on

paper, seem like a neat solution to the problem of 'inappropriate' scientific review by RECs. However, it does not address the root issue that ethical issues are often ethico-scientific in nature. I have argued earlier that I think ethical review ought to become part of scientific review. Without going this far, the system would do well to recognise a grey area, that there some ethical questions that are inextricably scientific in nature.

The aim of this thesis has been to do more than produce policy recommendations. I have sought to make sense of the spaces of LREC. Spaces that are, first and foremost, actual physical spaces. I have undertaken this research as part of a wider commitment to understanding ethics as emplaced and thus the methods for representing and thus intervening in ethical debates as reliant on empirical methods. A commitment that has borne fruit, both in the production of an account of LRECs and their deliberation and decision making and by contribution to a theorisation of geographies of (bio)ethics.

Appendices

Appendix 1 Table of LREC observations made

No entry (i.e. where a cell is left blank) indicates no data available.

Reference number	Date	Number interviews	Lay chair of vice-chair?	Number of members	Number of Lay members	Number of nurses	Regularity of meetings	Time of committee meetings	Average length of meetings (last 3 months) Up to..	Average applications per meeting (last 3 months)	Percentage of student research Up to..	Researchers Invited	Full time admin.
1	May 2002	2	Chair	13	4	1	Monthly	Evening	2 Hours	2	¼	Usually	Yes
2	July 2002	3	No	11	4	2	Monthly	Afternoon	3 Hours	4	½	Usually	Yes
2 (repeat observation)	November 2002	N/A											
4	December 2002	3	No	13	4	2	Monthly	Lunchtime	2 Hours	4	¼	Usually	No
5	June 2003	4	No	15	2	1	Monthly	Afternoon	3 Hours	10	¼	Occasionally	Yes
6	June 2003	6	No	12	5	5	Monthly	Varies	4 Hours	10	¾ - all	Occasionally	No
7	July 2003	4											
8	August 2003	5	Vice	21	7	2	Monthly	Evening	2 Hours	6	¼	Never	
9	August 2003	3											
10	September 2003	2											
11	September 2003	2	Chair	10	3	2	Monthly	Evening	2 Hours	3	¼	Occasionally	No
12	October 2003	1	Vice	9	2	1	Monthly	Evening	3 Hours	6	½	Usually	
13	October 2003	1	No	14	6	1	Monthly	Afternoon	3 Hours	4	¼	Usually	No

Reference number	Date	Number interviews	Lay chair of vice-chair?	Number of members	Number of Lay members	Number of nurses	Regularity of meetings	Time of committee meetings	Average length of meetings (last 3 months)	Average applications per meeting (last 3 months)	Percentage of student research	Researchers Invited	Full time admin.
14	October 2003	3	Chair	11	2	1	Monthly	Lunchtime	2 Hours	4	½	Occasionally	No
15	October 2003	0											
16	November 2003	1	No	18	7	2	Monthly	Lunchtime	2 Hours	7	¼	Occasionally	No
17	November 2003	2	No	17	4	4	Monthly	Lunchtime	3 Hours	5	¼	Usually	No
18	November 2003	2											
19	December 2003	1	No	12	3	1	Monthly	Lunchtime	2 Hours	5	½	Usually	
20	February 2004	1											

Appendix 2 Comparison of all committees and observed committees

Data from questionnaire survey
Data for Observed committees only available for 13 out of 20 committees

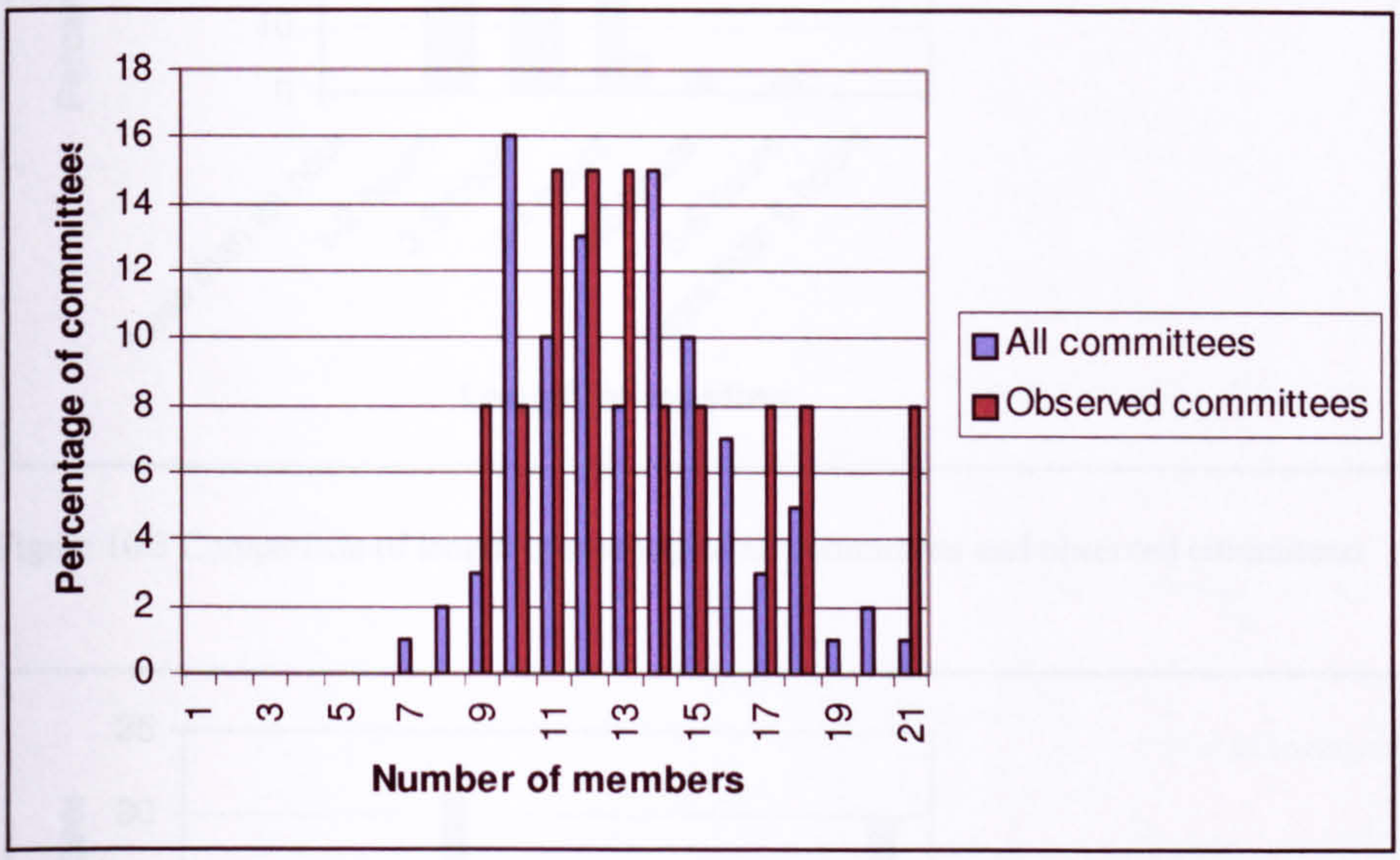

Figure 10.1 Comparison of the number of members in all committees and observed committees

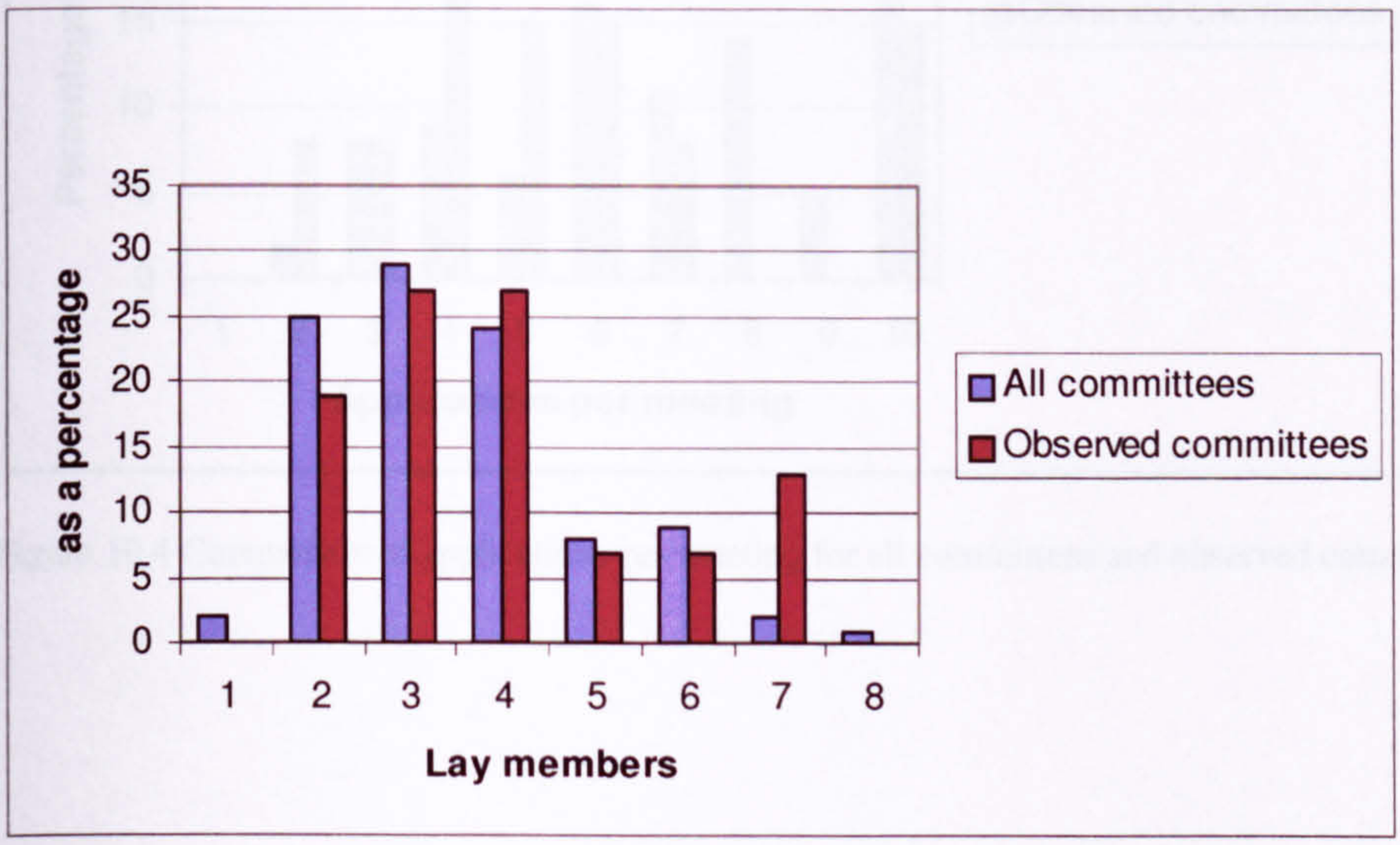

Figure 10.2 Comparison of number of lay members in all committees and observed committees

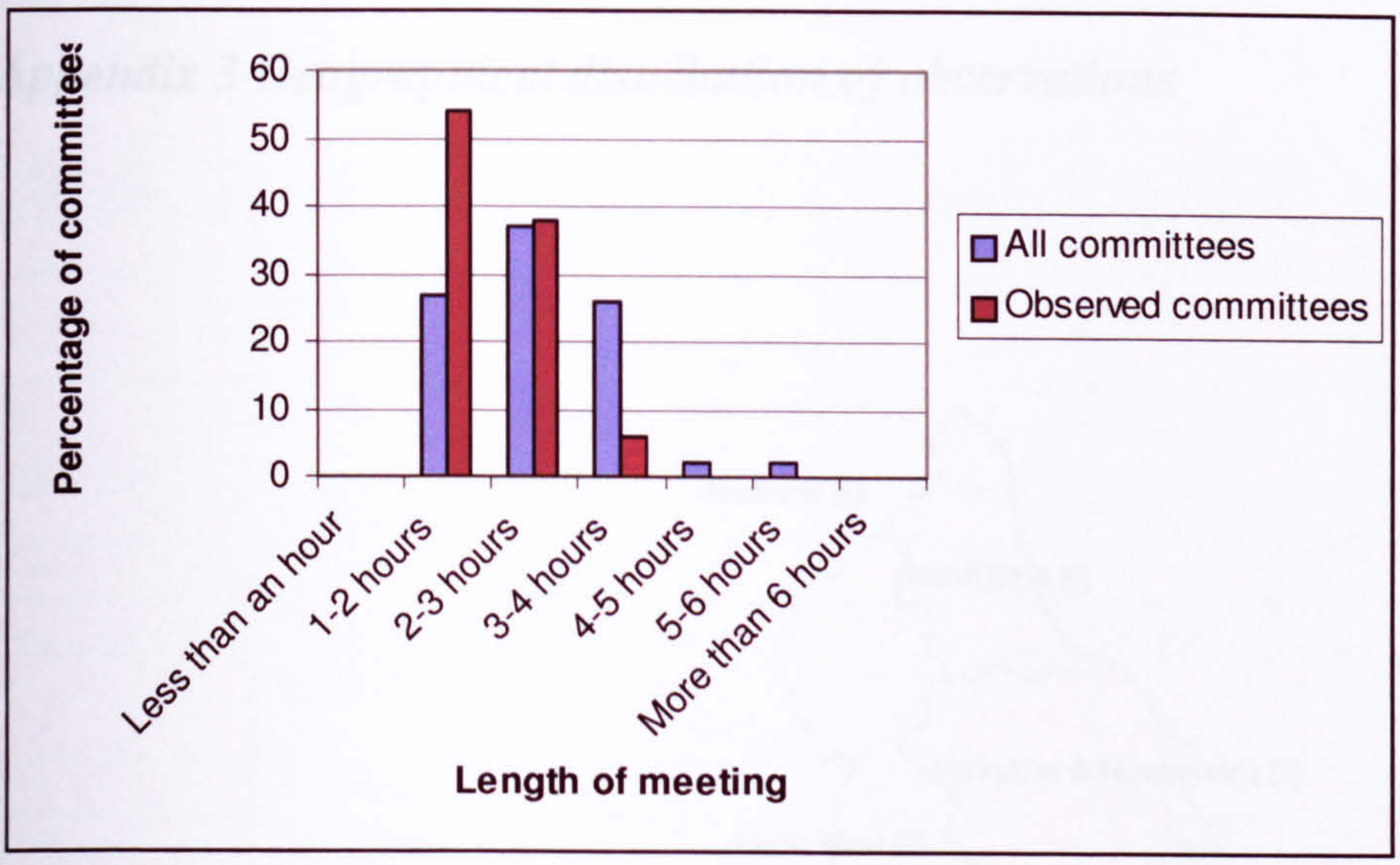

Figure 10.3 Comparison of length of meeting of all committees and observed committees

Figure 10.4 Comparison of applications per meeting for all committees and observed committees

Appendix 3 Geographical distribution of observations

Appendix 4 Table of Interviews

Interview	Position	Capacity	Gender	Retired?	Committee
1	Member	Lay	M	Retired	1
2	Member	Hospital staff, nurse	F		1
3	Chair	Non-clinical research	F		4
4	Member	Lay	F	Retired	
5	Member	Lay	F		2
6	Member	Lay	F	Retired	
7	Member	Hospital staff, nurse	F		2
8	Member	Lay	M	Retired	2
9	Member	Lay	F		
10	Member	Lay	F		4
11	Member	Research, nurse academic	F		4
12	Member	Lay	M		5
13	Member	Hospital staff, Consultant	F		5
14	Chair	Hospital Staff, Consultant	M		5
15	Member	Lay	F		5
16	Member	Research Nurse Academic	F		6
17	Member	Lay	F	Retired	6
18	Member	Hospital Staff, Consultant Researcher	F		6
19	Chair	Non-clinical research	F		6
20	Member	Lay,	F		6
21	Member	Lay	M		6
22	Member	Lay	F	Retired	8
23	Member	Lay,	F	Retired	8
24	Member	Hospital Staff, Consultant	F		8
25	Member	Non-clinical research	M		8
26	Member	Hospital staff	F		8
27	Member	Statistician	M		9

28	Member	Lay	F		9
29	Member	Non-clinical research	F		9
30	Member	Lay,	F	Retired	10
31	Member	Lay,	F		10
32	Member	Lay	M	Retired	11
33	Chair	Non-clinical research	M		11
34	Member	Statistician	M		12
35	Chair	Hospital staff, consultant	F		13
36	Member	Lay	F		14
37	Member	Lay	M	Retired	14
38	Chair	Lay	M	Retired	14
39	Member	Lay	M	Retired	16
40	Member	Hospital Staff, consultant	M		17
41	Chair	Hospital Staff, consultant	M		17
42	Member	Lay	M	Retired	18
43	Member	Hospital staff, consultant	M		18
44	Member	Lay	F	Retired	19
45	Member	Hospital Staff, Consultant	F		20
46	Member	Hospital Staff, Consultant	F		7
47	Member	Lay	F		7
48	Member	Lay	F		7
49	Member	Hospital Staff, Consultant	F		7

Significant occupations of the lay members I interview:

Bioethicist	2
Lawyer/ Judge	5 (1 of who was retired)
Hospital Chaplin	1
Retired medical staff	8
Retired researchers	4
Retired public sector	3

Appendix 5 Interview protocol (version 1)

Interview schedule version 1 01/07/02

BIBILOGRAPHY
What committee are you on?
In what role?
How long have you been on the committee? (Has the committee changed over time?)
Why did you become a member? **How** What was the process?
What was your experience of medical research before joining the committee?
Do you live/work **locally**?
Do you take part in other community activities? (churches, community groups?)

EXPERIENCE ON REC
Can you remember what your initial experience/ impressions were?
About the committee: How often does your committee meet?
What is the workload like?
What types of research to review?
Do you know how long the committee has existed?

Decisions:
How does your committee make its decisions?
Interview researchers? Conesus? Votes?

What other **guidelines** are you aware of/ do you use? How do you use them?

How do expert and lay members interact on your committee?
In your opinion what contribution to **expert** members make?
In your opinion what contribution to **lay** members make?
And are these unique contributions? (in other words: do the lay members contribute something that experts couldn't?)
In the governance it says that lay members are non representative, what does that mean?
What is ratio of approvals to rejections?

Personal decision-making: What do you look for in the review process? Has that changed over time?

What are the responsibilities of being a member?
What skills do you bring to the review process?
Do you feel adequately supported?

Bureaucratic context:
What training have you received?
Do you have any contact with other LRECs?
Has Gafrec made a difference to how your committee operates?
COREC?

OPINIONS ABOUT MEDICAL RESEARCH
What counts as ethical research? What are the threats

to ethical research? What are the opportunities?
What **role** does a LREC have?

Locality: One of the things that was written in the BMJ about the need for consistency in LREC review was that research that is ethical in Land's End surely must be ethical in John O'Groats. Do you agree?

What do you think is the role of **guidelines** in an ethical review?
Where does responsibility for the ethics of research rest?

What are the **strengths and weaknesses** of LREC review? Accountability ?

Do you have a sense about how LRECs are **viewed by researchers** and by the **public?**

Expert members: what are your experiences of
>medical research? Informed consent? Have
>understandings of ethical research changed over time?
>Have understandings or practices changed because of
>being on the committee?

Appendix 6 Interview protocol (version 2)

Interview schedule version 2 16/12/02

BIOGRAPHY
What committee are you on?
In what role?
How long have you been on the committee? (Has the committee changed over time?)
Why did you become a member? **How** What was the process?
What was your experience of medical research before joining the committee?
Do you live/work **locally**?
Do you take part in other community activities? (churches, community groups?)

EXPERIENCE ON REC
Can you remember what your initial experience/ impressions were?
About the committee: **How often does your committee meet?**
What is the workload like?
What types of research to review?
Do you know how long the committee has existed?

Personal decision-making: What do you look for in the review process? Has that changed over time?

What are the responsibilities of being a member?
What skills do you bring to the review process?
Do you feel adequately supported?

Bureaucratic context:
What training have you received?
Do you have any contact with other LRECs?
Has Gafrec made a difference to how your committee operates?
COREC?

CONTRIBUTION TO THE MEETING
Was that a **normal meeting**? In terms of length? No. of protocols? Issues raised?
How does your committee make its decisions?
Interview researchers? Conesus? Votes?
What is ratio of approvals to rejections?

Did anything surprise you?
What were the issues raised?
Were you happy with the outcomes?

In what way is the committee a **local** research ethics committee? Is that important?

OPINIONS ABOUT MEDICAL RESEARCH
Go through notes on the meeting an identify issues to be discussed with informant under these headings (and any other that field notes include)

Local
Layness
Science-ethics boundary
Harm (risk/benefit assessment)
Information/consent
Patient perspective

End with question about what LRECs do well.
Ask them if they have anything else that they want to say, or ask.

Appendix 7 My participant information sheet

KING'S College LONDON

Geographies of Trust and Consent in Medical Research

I am inviting you to take part in my PhD. research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for taking the time to read this Information Sheet.

What is the purpose of the study?

My research project examines the regulation of medical research as practiced in the review of research protocol and patient information by Local Research Ethics Committees (LRECs). Scandals concerning unethical medical research have lead to a reassessment of doctor-patient relationships. In the face of increased public mistrust, bioethicists, government agencies and medical researchers themselves have been challenged to ensure that the medical research is ethically sound and publicly acceptable. Within the context of a marked social change towards either a 'litigation culture' or a culture of informed and empowered patients, depending on your perspective, the effective regulation of medical research is becoming both more difficult and vital. The Department of Health has sought to address public concerns exemplified by the recent scandals at Alder Hey and North Staffordshire Hospitals by issuing new 'Governance Arrangement for Research Ethics Committees'. The Governance prescribes an accountable review by both professional and lay people, in which an informed consent by subjects is central. This research project describes the formation of UK national policy and guidelines and how this policy is enacted and understood by LRECs. Using analysis of observation of committee meetings and interviews with both committee members and researchers I seek to elucidate the role that lay members have on the committees and understandings of an 'informed consent' that are expressed and enshrined.

This study addresses the important question of how to best ensure ethical medical research. The context for this study includes the increased attention that medical research scandals are being given in the media. This is both a reflection and a cause of the reassessment of medical paternalism. Motivation also comes from the increasing attention paid to the regulation of medical research and, in particular, 'informed consent' by the Department of Health and Professional Bodies, such as the BMA. Theoretically, this project fits into literature on public understanding of science and risk, literature on professions, bureaucracy and regulation and literature on participatory democracy. There has been little empirical research done on LRECs. This research project seeks to address gaps in the literature on bioethics that conventionally has been studied at a very abstract level and from a US perspective. It seeks to 'test-out' theories from the theoretical literature mentioned above, in the site of LRECs. I believe that a site-specific description of bioethical issues will have much to say to the technically prescriptive professional literature and the ethically normative bioethics literature.

Why have I been chosen?

I am approaching you for an interview because I am interested in talking to people who sit on LRECs.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you are of course free to change your mind; to withdraw at any time and without giving a reason.

What will happen if I agree to take part?

I will arrange a time and a place with you for the interview. In the past interviews have taken place at peoples' places of work and have lasted approximately an hour. This though is entirely at your convenience. In the interview I will ask you about your experiences of LREC membership and your views on ethical medical research. The interview will be semi-structured, which means you are free to describe experiences and opinions that I do not ask you about. If you do not want to answer any of the questions that I do ask that is fine. At the end of the interview I will ask you if you would mind being approached in the future course of this research, if I have further questions, and to comment of my findings. The research is due to finish in September 2004. You are free to decline to be contacted in the future course of this research and you are free to change you mind at any time.

What are the possible disadvantages and risks of taking part?

Taking part in this study requires your time in taking part in the interview: approximately one hour. If you agree to be further approached you will be asked to give up more time to answer further questions, although this shouldn't take more than ten to fifteen minutes over the 'phone or email.

What are the possible benefits of taking part?

There are no direct personal benefits in taking past in this study. The research findings, though, might be of interest to you.

What if something goes wrong?

If you are unhappy with anything about the interview process you can discuss it with either me or my supervisor:

Dr. David Demeritt
Geography Department
King's College, London
The Strand
WC2R 2LS

020 7848 2622

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. You will be asked in the interview if you mind our conversation being audio taped. If you do not mind the tape will be transcribed with all identifying information removed and then the tapes then wiped. If you do not want our conversation to be taped I will write notes, which will also have all identifying information removed. I will write to you after the interview putting our agreement in writing.

What will happen to the results of the research study?

This research study is for my PhD, which will be publicly accessible through the University of London Library. The findings are likely to be presented at academic conferences and submitted to peer reviewed journals. There is also a possibility that they might be included in academic books on the subject.

Who is funding the research?

This study is funded by a University of London, Triangle Trust scholarship.

Who has reviewed the study?

My PhD panel has reviewed this research.

Contact for Further Information

Sarah Dyer
Geography Department
King's College, London
The Strand
London
WC2R 2LS

sarah.e.dyer@kcl.ac.uk

020 7738 3038

Appendix 8 Additional research activities

I served on the Tavistock and Portman LREC as a lay member for 18 months.

In the course of this research I spoke to the following people:

Clare Foster, past editor of the *Manual for Research Ethics Committees*, interview recorded, 04/02
Sue Ecstein, current editor *Manual for Research Ethics Committees*, interview unrecorded, 01/07/02
John Richardson, COREC, 08/01/02
Richard Nicholson, Editor of the *Bulletin of Medical Ethics*, 01/03

As a lay member I attended the following meetings:

Association Research Ethics Committee meeting, 05/07/02
Association Research Ethics Committee meeting, 10/09- 13/09/02
REC training 30/10- 31/10/03

Appendix 9 Questionnaire instructions

Department of Geography,
School of Social Science and Public Policy,
King's College, London,
The Strand,
London WC2R 2LS

Instructions

Thank you for your help handing out these questionnaires to your committee.

At the beginning of the next convenient meeting, please could you:

- Give a 'Questionnaire to Committee Members' to each member of the committee
- Give a 'Questionnaire to Administrators' to the administrator
- At the end of the meeting collect completed questionnaires
- Return completed questionnaires, along with your last annual report, in the SAE provided
- If committee members are absent from this meeting, give them the 'Questionnaire to Committee Members' at the next meeting and let them know I can also provide an electronic version of the form if that is more convenient for them.

Thank you again. If you have any questions or comments I can be contact on the above address or at sarah.e.dyer@kcl.ac.uk.

Appendix 10 Questionnaires

(with coding)

RESPONDENT NUMBER - PUT IN AS NUMBER e.g. 256

Questionnaire to Committee Members

You are invited to take part in a survey being conducted as part of a PhD project (Geographies of Trust and Consent in Medical Research). This questionnaire is being sent to all LREC members in the UK in order to build a comprehensive picture of the composition of LRECs. Forms will be stored securely and destroyed as soon as data has been processed. Publication of this material will contain no identifying information and will be made available to all LRECs.

You are under no obligation to complete this questionnaire. It should take no more than 2 minutes to complete. Please can you **return the completed form to your administrator** at the end of the meeting or send it to the address given over leaf. **Thank you for your help.**

Q1. Which LREC do you sit on? Code from attached sheet (1-218)_____

Q2. How many years have you sat on this committee? Enter as is - i.e. whole number (0=0.5 year)

Q3. What is your position on this committee? PLEASE CIRCLE

Chair (1)	Vice-chair (2)	Member (3)

Q4. In what capacity do you sit on this committee? PLEASE CIRCLE

Lay member (1)	Nurse (2)	GP (3)	Pharmacist (4)	Medical consultant (5)
Medical profession (other) (6)	Social scientist (7)	Statistician (8)	Unsure (9)	Other (specify) (10) AND AT Q4B

WRITE IN CAPACITY IF 'OTHER' ABOVE Code UNDER Q4B

CREATE LIST, GROUPING RELEVANT JOBS TOGETHER. LIST STARTS AT 11

Q5. Do you sit on any other Research Ethics Committees? PLEASE CIRCLE

No (1)	Yes (Please specify below) (2)

WRITE IN NAME IF 'YES' ABOVE Code under Q5B up to three mentions.

Use attached sheet (codes 1-218)

Q6. How many days of LREC training have you attended in the last **2 years**? PLEASE CIRCLE

0	1	2	3	4	5	6	7	8	9	10 + (10)

Q7. In the past **5 years** have you conducted any clinical research involving human subjects? PLEASE CIRCLE

Yes (1)	No (2)

Q8. In the past **5 years** have you conducted any other research involving human subjects? PLEASE CIRCLE

Yes (1)	No (2)

Q9. In the past **5 years** have you taken part in Health or Social Services research as a subject? PLEASE CIRCLE

Yes (1)	No (2)

Q10. Are you male or female? PLEASE CIRCLE

Male (1)	Female (2)

Q11. How old are you?

25 or less (1)	26-35 (2)	36-45 (3)	46-55 (4)	56-65 (6)	66-75 (7)	76 + (8)

Q12. What is your occupation? (If you are retired please state you occupation on retirement)

Code_____

CREATE LIST, GROUPING RELEVANT OCCUPATIONS TOGETHER.
LIST STARTS AT 1

Q13. What is your highest formal educational qualification? PLEASE CIRCLE

No formal qualifications (1	O levels/GCSEs NVQ level 2 (2)	A levels/ NVQ 3 (3)	First degree/ NVQ 5 (4)	Higher degree (5)

Q14. Do you have any of the follow professional qualifications?
PLEASE CIRCLE CODE UPTO 3 MENTIONS AT Q14(1), 14(2), 14(3)

Qualified Teacher Status (1)	Qualified Medical Doctor (2)	Qualified Dentist (3)	Qualified Nurse, Midwife, Health Visitor (4)	Qualified Solicitor/ Barrister (5)	Qualified Religious preacher/ Leader (6)	Other (specify) (7) AND AT Q14B BELOW	None (8)

WRITE IN IF 'OTHER' ABOVE Code _____

CREATE LIST, GROUPING RELEVANT QUALIFICATIONS TOGETHER.

LIST STARTS AT 9

Q15. What is your ethnic group? PLEASE CIRCLE (OPTIONAL)

Asian/Asian British (1)	Black/Black British (2)	Chinese/British – Chinese (3)	White (4)	Other (specify) (5) AND Q15B

WRITE IN IF 'OTHER' ABOVE Code _____

CREATE LIST, GROUPING RELEVANT ETHNICITIES TOGETHER.
LIST STARTS AT 6

Q16. Would you be happy to be approached to take part in an hour in-depth interview? In this interview we will be looking at the role of LRECs in the context of medical ethics in the UK. All of your views will remain entirely confidential. If you are happy to help please provide contact details or contact me at the address below.
CODE THOSE WHO HAVE FILLED IN CONTACT DETAILS AS "YES" = 1
CODE THOSE WHO HAVE NOT PROVIDED DETAILS AS "No" = 2

Name
Address

Telephone number
E-mail

Thank you for taking the time to answer these questions.
Sarah Dyer (Lay Member, Tavistock and Portman LREC)

For further information please contact:
Sarah Dyer

Department of Geography,

King's College London,
The Strand, London WC2R 2LS

RESPONDENT NUMBER - PUT IN AS NUMBER e.g. 45

Questionnaire to Administrators

Q1. Which committee are you filing this form out with reference to?

_____

Code from attached sheet (1-218)

Q2. How many members are there on this committee?_____

Enter as is - i.e. whole number

Q3. How many of the following are there on this committee:

Lay members?_____Enter as is i.e. whole number AT Q3A

Nurses members?_____ Enter as is i.e. whole number AT Q3B

Statisticians?_____ Enter as is i.e. whole number AT Q3C

GPs?_____ Enter as is i.e. whole number AT Q3D

Pharmacists?_____ Enter as is i.e. whole number AT Q3E

Q4. Is either the chair or the vice-chair of this committee a lay member?
PLEASE CIRCLE

Chair (1)	Vice-chair (2)	Both (3)	Neither (4)

Q5. Does this committee have a website? PLEASE CIRCLE

Yes (1)	No (2)

Q6. Does the committee produce an annual report? PLEASE CIRCLE
If so, please include last report in the return envelope

Yes (1)	No (2)

Q7. Is this committee a member of the Association of Research Ethics Committees? PLEASE CIRCLE

Yes (1)	No (2)	Not presently a member (3)	Unsure (4)

Q8. How often does the committee meet? PLEASE CIRCLE

More regularly than monthly (1)	Monthly (2)	Every six weeks (3)	Less than every six weeks (4)

Q9. When does the committee meet? PLEASE CIRCLE

Mornings (1)	Lunchtimes (2)	Afternoons (3)	Evenings (4)	Varies (5)

Q8. On average in the **last 3 months** has each meeting lasted? PLEASE CIRCLE

1 hour or less (1)	Less than 2 hours (2)	Less than 3 hours (3)	Less than 4 hours (4)	Less than 5 hours (5)	More than 5 hours (6)

Q11. How does this compare with the length of the previous year's meetings?
PLEASE CIRCLE

An increase (1)	About the same (2)	A decrease (3)	Unable to say (4)

Q12. On average, in the **last 3 months** how many protocols have been reviewed in each meeting? (Please include all protocols) PLEASE CIRCLE

1 (1)	2 (2)	3 (3)	4 (4)	5 (5)	6 (6)	7 (7)	8 (8)	9 (9)	10 (10

Q13. How does this compare with number in the previous year's meetings? PLEASE CIRCLE

An increase (1)	About the same (2)	A decrease (3)	Unable to say (4)

Q14. How many times **in the past year** has your committee sought external expert advise on a proposal? PLEASE CIRCLE

Never (1)	Once (2)	2-5 times (3)	6-10 (4)	11-20 (5)	21 or more (6)

Q15. What percentage of protocols that your committee sees are student projects? PLEASE CIRCLE

None (1)	1-25% (2)	26-50% (3)	51-75% (4)	75-99% (5)	All (6)

Q16. What percentage of protocols is approved without modification?
PLEASE CIRCLE

None (1)	1-25% (2)	26-50% (3)	51-75% (4)	75-99% (5)	All (6)

Q17. What percentage of protocols is approved subject to chair's action?
PLEASE CIRCLE

None (1)	1-25% (2)	26-50% (3)	51-75% (4)	75-99% (5)	All (6)

Q18. What percentage of protocols does a full committee review more than once?
PLEASE CIRCLE

None (1)	1-25% (2)	26-50% (3)	51-75% (4)	75-99% (5)	All (6)

Q19. Does your committee invite researchers to attend meetings?
PLEASE CIRCLE

Never (1)	Occasionally (2)	Usually (3)	Always (4)

Q20. How many hours per week are you contracted for as an administrator of this committee?

_____

_____

Enter as is - i.e. whole number

Q21. Are you the administrator to more than one committee?
PLEASE CIRCLE

No (1)	Yes, one other (2)	Yes, more than one other (3)

Q22. How many days of LREC training have you attended in the last 2 years?
PLEASE CIRCLE

0 (0)	1 (1)	2 (2)	3 (3)	4 (4)	5 (5)	6 (6)	7 (7)	8 (8)	9 (9)	10 + (10)

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